STATE OF CONNECTICUT
DEPARTMENT OF PUBLIC HEALTH

Raul Pino, M.D., M.P.H.
Commissioner

Dannel P. Malloy
Governor

Nancy Wyman
Lt. Governor

Healthcare Quality And Safety Branch

August 14, 2018

Michael Collins, Administrator
Manchester Memorial Hospital
71 Haynes Street
Manchester, CT 06040

Dear Mr. Collins:

This is an amended edition of the violation letter originally sent on August 7, 2018.

Unannounced visits were made to Manchester Memorial Hospital commencing on February 26, 2018 and concluding on June 6, 2018 by representatives of the Facility Licensing and Investigations Section of the Department of Public Health for the purpose of conducting multiple investigations.

Attached are the violations of the Regulations of Connecticut State Agencies and/or General Statutes of Connecticut which were noted during the course of the visits.

An office conference has been scheduled for August 22, 2018 at 10:00AM in the Facility Licensing and Investigations Section of the Department of Public Health, 410 Capitol Avenue, Second Floor, Hartford, Connecticut. Should you wish to retain legal representation, your attorney may accompany you to this meeting. Please be prepared to discuss those violations Identified with an asterisk.

You may wish to dispute the violations and you may be provided with the opportunity to be heard. If the violations are not responded to by August 8, 2018 or if a request for a meeting is not made by the stipulated date, the violations shall be deemed admitted.

Please prepare a written Plan of Correction for the above mentioned violations to be presented at this conference.

Each violation must be addressed with a prospective Plan of Correction which includes the following components:

(1) The measures that the institution intends to implement or systemic changes that the institution intends to make to prevent a recurrence of each identified issue of noncompliance;
(2) the date each such corrective measure or change by the institution is effective;
(3) the institution's plan to monitor its quality assessment and performance improvement functions to ensure that the corrective measure or systemic change is sustained; and
(4) the title of the institution's staff member that is responsible for ensuring the institution's compliance with its plan of correction.

Alternate remedies to violations identified in this letter may be discussed at the office conference. In addition, please be advised that the preparation of a Plan of Correction and/or its acceptance by the Department of Public Health does not limit the Department in terms of other legal remedies, including but not limited to, the issuance of a Statement of Charges or a Summary Suspension Order and it does not preclude resolution of this matter by means of a Consent Order.

DATE(S) OF VISIT: June 6, 2018

THE FOLLOWING VIOLATION(S) OF THE REGULATIONS OF CONNECTICUT STATE AGENCIES AND/OR CONNECTICUT GENERAL STATUTES WERE IDENTIFIED

Should you have any questions, please do not hesitate to contact this office at (860) 509-7400.

Respectfully,

Susan Newton, RN, BS
Supervising Nurse Consultant
Facility Licensing and Investigations Section

SHN:mb

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The following is a violation of the State of Connecticut Public Health Code Section 19-13-D3 (b) Administration (2) and/or (c) Medical Staff (2)(B) and/or (c)(4)(A) and/or (i) General (6).

1. *Based on a review of the clinical record, staff interviews, and a review of hospital documentation for one of three patients (Patient #1), who was a high risk obstetrical patient that required an emergency cesarean section, the hospital's governing body failed to ensure that the medical staff was accountable to the governing body for the quality of care provided to the patients and/or the hospital's Quality Assurance and Performance Improvement (QAPI) failed to implement preventive actions and mechanisms subsequent to a perinatal risk assessment dated 12/27/17 to ensure patient safety. The finding includes:
   a. Patient #1 was admitted to the hospital on 1/16/18 at 2:43pm with complaints of edema, elevated blood pressure and fetal demise after being evaluated in a physician's office. On arrival, Patient #1's blood pressure was 160/100 and 203/132. Patient #1 had no visual changes, headache, temperature was 98.2 (normal range) and had no epigastric pain on admission. Patient #1 was diagnosed with preeclampsia, intrauterine fetal demise and was a high risk pregnancy. Patient #1 received Hydralazine 10mg (to reduce blood pressure) and Cervidil was placed at 5:23pm.
   Review of the clinical record from 1/16/18-1/18/18 identified that Patient #1's blood pressure's intermittently continued to be elevated with blood pressures noted on 1/16/18 at 7:33pm 159/100, 8:50pm 167/101, 630pm 174/106, the patient complained of blurred vision. The goal was to keep blood pressure less than 160/100. Patient #1 was given multiple doses of Hydralazine and Magnesium Sulfate IV was started. Further review identified that the patient was being managed by multiple certified midwives (CSM) from admission through discharge.
   On 1/17/18 at 8:30am, Pitocin IV (to induce labor) was started. On 1/17/18 at 12:30pm, the vaginal balloon catheter was inserted (for cervical dilation and ripening). Further review identified that Patient #1's blood pressures continued to be elevated on 1/18/18 at 8:31am 167/101 with complaints of blurred vision and at 1/18/18 at 9:28am 161/103. Further review identified that on 1/18/18 at 7:56pm, the Pitocin IV was discontinued since the patient was at the maximum dose of 20mg and labor was not progressing. Patient #1's blood pressures continued to be elevated at 8:31am 167/101 with complaints of blurred vision and at 1/18/18 at 9:28am 161/103. On 1/18/18 at 9:10am, the vaginal balloon catheter fell out (19 hours later) after insertion. Further review identified that although the MD #3 was called and made aware of the patient's condition which included an elevated blood pressure and blurred vision, the physician was not in the building managing the high risk patient and/or any OB physician in the hospital.
   Review of the clinical record identified that on 1/18/18 at 8:25pm, Patient #1 became hypotensive with a blood pressure of 81/48, tachycardia at 110 and a temperature of 103 degrees Fahrenheit. Anesthesia was called in to the room and a fluid bolus was started. The on-call obstetrician (MD #1) was called in and arrived 40 minutes later, MD #1 evaluated the patient and a diagnosis of chorioamnionitis (intra-amniotic infection) was made with a decision to perform an emergency Cesarean Section. Patient #1 delivered

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a stillborn on 1/18/18 at 9:48pm. Further review failed to identify that the Rapid Response Team was activated (team of providers that respond to hospitalized patients with early signs of deterioration) by the staff when the patient's status had deteriorated in accordance with hospital policy.

Review of the progress note dated 1/19/18 identified that MD #1 was called to the intensive care unit (ICU) by the ICU attending (MD #2) after the patient's blood pressures continued to drop. Blood pressures reported were 83/70, 56/41 and 71/38 with the patient on the maximum dose of four vasopressors (Levophed, Dopamine, Neo-Synephrine and Vasopressin drips) Patient #1 intubated, IV antibiotics and multiple doses of blood products were given. Patient #1 was presumed to be in septic shock and DIC from chorioamnionitis. Further review identified that after a discussion with the family a decision was made to transfer the patient to a higher level of care due to the patient's deteriorating condition. Patient #1 was airlifted to Hospital #2 at 3:55am. On 1/19/18, Patient #1 when into a cardiac arrest at 7:00am and expired at 8:25am.

Review of the autopsy report identified the cause of death as severe preeclampsia leading to intrauterine fetal demise, leading to a cesarean section complicated by septic shock with disseminated intravascular coagulation.

Interview with the Chief Nursing Officer on 3/7/18 identified that the hospital had an external consultant review of obstetrical services in 12/2017 identified concerns regarding medical management of high risk pregnancies.

Interview with the Chief Medical Officer on 3/7/18 identified that the physician and not a CNM should have been at the hospital to care for high risk pregnancy patients and that Patient #1 had went too long before having a C-Section. Further interview identified that the hospital was developing a protocol for fetal demise and for the management of the cervical balloon catheter for cervical ripening by the provider. MD #2 indicated that when labor is extended and when the cervical balloon catheter was left in with no staff monitoring the balloon catheter, the risk of infection increased and the Patient #1 became septic.

Interview with the Chief of Obstetrics on 3/7/18 identified that the physician would need to be at the hospital for any high risk patient. Further interview identified that balloon catheter needed to be removed after twelve hours and he/she would have performed the C-Section in the afternoon on 1/18/18 since the patient had no change in progression of labor and was at the maximum dose of Pitocin. MD #1 indicated that he/she had developed a new level system recommended from ACOG (American Colleges of Obstetricians and Gynecologist), however had not implemented it yet.

Review of facility policy entitled "Management of Preeclampsia and Eclampsia" identified that the practitioner will be notified within 30 minutes of the arrival of all gravid patients that present to the family birthing center with a blood pressure greater than 140mmHg systolic or greater than 90mmHg diastolic occurring with two readings taken at least 15 minutes apart. In addition, the practitioner will be requested at the bedside for any patient with a blood pressure greater than 160mmHg systolic or greater than 100mmHg diastolic occurring with two readings taken at least 15 minutes apart.

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Review of the facility policy entitled "Rapid Response Team" identified that a staff member will consider activating the Rapid Response Team for any of the changes in a patient's condition which includes an acute change in a systolic blood pressure or any changes in the patient's condition if a staff member feels the patient's condition is deteriorating.
Review of facility policy entitled "Cervical Ripening" identified that the balloon catheter may be expelled when cervical dilation occurs, however, the balloon catheter must be removed no longer than 12 hours after insertion.
Review of the Certified Nurse Midwife (CNM) privileges identified that the CNM will manage the care of normal newborns and women, antepartally, intraparatally and postpartally. Further review indicated that the CNM will care for patients of the practice according to agreed upon protocols and in consultation with the physician.
Review of hospital perinatal risk assessment conducted on 12/13-12/14/17 and received on 12/27/17 identified that the obstetrical department had no clear guidelines for on-call providers related to active labor, high risk oversight of Certified Nurse Midwife (CNM) or other elective surgeries. In addition, the assessment indicated that there were no specific written guidelines that outline what conditions for which either the CNM or Family Medicine Specialists need to consult, co-manage or refer to obstetricians. In addition, staff were unclear on the hospital wide use of rapid response process and/or codes. Further review failed to identify that the consultant's recommendations to mitigate risk regarding the roles and responsibilities of the medical staff including the medical management of active labor and/or high risk pregnancies were implemented.
Review of the governing body bylaws identified that the operation committee of the governing body will oversee and direct all quality improvement activities of the hospital, including but not limited to assuring that there are ongoing programs to reduce medical errors and provide that all quality improvement activities are evaluated, assure that safety expectations are established, measure and assess the hospital's ongoing performance.
Interview with the Quality Manager on 3/2/18 at 1:55 PM indicated although a root cause analysis was initiated immediately following the event on 1/18/18, staff interviews had not been conducted, and a comprehensive plan had not been completed.
Subsequent to surveyor inquiry on 3/2/18, the facility had submitted an immediate action plan to the state agency. The action plan included re-educating staff on caring for a preeclamptic patient, timely removal of a cervical balloon catheter and when to activate the rapid response team, reviewing of policies and procedures pertaining to family birthing and reviewing the roles and responsibilities of the medical and family birthing staff.

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2. *Based on clinical record reviews, review of policies and procedures and interviews with facility personnel for one of six sampled patients (Patient #1), the facility failed to ensure that the medical staff were accountable for the quality of care provided to a obstetrical patient who was determined to be a high risk pregnancy.
The medical staff failed to manage and provide the quality of care to a high risk pregnant patient; failed to ensure that a vaginal balloon catheter was removed after twelve hours to reduce the risk of an infection; failed to timely implement recommendations from the perinatal risk assessment conducted in 12/2017 for patient's that present to the hospital in active labor and/or high risk pregnancy which indicated that the hospital had no clear guidelines for on-call providers related to active labor, high risk oversight of Certified Nurse Midwife (CNM) or other elective surgeries. In addition, the assessment indicated that there were no specific written guidelines that outline what conditions for which either the CNM or Family Medicine Specialists need to consult, co-manage or refer to obstetricians. Also, staff were unclear on the hospital wide use of codes; failed to ensure that a Certified Nurse Midwife (CSM) would only provide care for normal newborns and women, antepartally, intraparatally and postpartally; and failed to activate the Rapid Response Team when the patient's status deteriorated. The findings include:

a. Patient #1 was admitted to the hospital on 1/16/18 at 2:43pm with complaints of edema, elevated blood pressure and fetal demise after being evaluated in a physician's office. On arrival, Patient #1's blood pressure was 160/100 and 203/132. Patient #1 had no visual changes, headache, temperature was 98.2 (normal range) and had no epigastric pain on admission. Patient #1 was diagnosed with preeclampsia, intrauterine fetal demise and was a high risk pregnancy. Patient #1 received Hydralazine 10mg (to reduce blood pressure) and Cervidil was placed at 5:23pm.
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On 1/17/18 at 8:30am, Pitocin IV (to induce labor) was started. On 1/17/18 at 12:30pm, the vaginal balloon catheter was inserted (for cervical dilation and ripening). Further review identified that Patient #1's blood pressures continued to be elevated on 1/18/18 at 8:31am 167/101 with complaints of blurred vision and at 1/18/18 at 9:28am 161/103.
Further review identified that on 1/18/18 at 7:56pm, the Pitocin IV was discontinued since the patient was at the maximum dose of 20mg and labor was not progressing. Patient #1's blood pressures continued to be elevated at 8:31am 167/101 with complaints of blurred vision and at 1/18/18 at 9:28am 161/103. On 1/18/18 at 9:10am, the vaginal balloon catheter fell out (19 hours later). Further review identified that although the MD #3 was called and made aware of the patient's condition, the physician was not in the building managing the high risk patient and/or any OB physician in the hospital.

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Review of the clinical record identified that on 1/18/18 at 8:25pm, Patient #1 became hypotensive with a blood pressure of 81/48, tachycardia at 110 and a temperature of 103 degrees Fahrenheit. Anesthesia was called in to the room and a fluid bolus was started. The on-call obstetrician (MD #1) was called in and arrived 40 minutes later, MD #1 evaluated the patient and a diagnosis of chorioamnionitis (intra-amniotic infection) was made with a decision to perform an emergency Cesarean Section. Patient #1 delivered a stillborn on 1/18/18 at 9:48pm. Further review failed to identify that the Rapid Response Team was activated (team of providers that respond to hospitalized patients with early signs of deterioration) by the staff when the patient's status had deteriorated in accordance with hospital policy.

Review of the progress note dated 1/19/18 identified that MD #1 was called to the intensive care unit (ICU) by the ICU attending (MD #2) after the patient's blood pressures continued to drop. Blood pressures reported were 83/70, 56/41 and 71/38 with the patient on the maximum dose of four vasopressors (Levophed, Dopamine, Neo-Synephrine and Vasopressin drips) Patient #1 intubated, IV antibiotics and multiple doses of blood products were given. Patient #1 was presumed to be in septic shock and DIC from chorioamnionitis. Further review identified that after a discussion with the family a decision was made to transfer the patient to a higher level of care due to the patient's deteriorating condition. Patient #1 was airlifted to Hospital #2 at 3:55am. On 1/19/18, Patient #1 when into a cardiac arrest at 7:00am and expired at 8:25am. Review of the autopsy report identified the cause of death as severe preeclampsia leading to intrauterine fetal demise, leading to a cesarean section complicated by septic shock with disseminated intravascular coagulation.

Interview with the Chief Nursing Officer on 3/7/18 identified that the hospital had an external consultant review of obstetrical services in 12/2017 identified concerns regarding medical management of high risk pregnancies.

Interview with the Chief Medical Officer on 3/7/18 identified that the physician should have been at the hospital to care for high risk pregnancy patients and that Patient #1 had went before having a C-Section. Further interview identified that the hospital was developing a protocol for fetal demise and for the management of the cervical balloon catheter for cervical ripening by the provider. MD #2 indicated that when labor is extended and when the cervical balloon catheter was left in, the risk of infection increased and the Patient #1 became septic.

Interview with the Chief of Obstetrics on 3/7/18 identified that the physician would need to be at the hospital for any high risk patient. Further interview identified that balloon catheter needed to be removed after twelve hours and he/she would have performed the C-Section in the afternoon on 1/18/18 since the patient had no change in progression of labor and was at the maximum dose of Pitocin. MD #1 indicated that he/she had developed a new level system recommended from ACOG (American Colleges of Obstetricians and Gynecologist), however had not implemented it yet.

Although the hospital hired a consultant in 12/2017 who reviewed the medical management of high risk pregnancies, the consultant recommended that there was no clear guidelines for on-call providers related to active labor, high risk oversight of Certified Nurse Midwife (CNM) or other elective surgeries. In addition, the assessment indicated that there were no specific written guidelines that outline what conditions for which either the CNM or Family Medicine Specialists need to consult, co-manage or refer to obstetricians. Also, staff were unclear on the hospital wide

use of codes. Further review failed to identify that any of the recommendations were implemented to mitigate the risk regarding the medical management of active labor and/or high risk pregnancies.
Review of facility policy entitled "Management of Preeclampsia and Eclampsia" identified that the practitioner will be notified within 30 minutes of the arrival of all gravid patients that present to the family birthing center with a blood pressure greater than 140mmHg systolic or greater than 90mmHg diastolic occurring with two readings taken at least 15 minutes apart. In addition, the practitioner will be requested at the bedside for any patient with a blood pressure greater than 160mmHg systolic or greater than 100mmHg diastolic occurring with two readings taken at least 15 minutes apart.
Review of the facility policy entitled "Rapid Response Team" identified that a staff member will consider activating the Rapid Response Team for any of the changes in a patient's condition which includes an acute change in a systolic blood pressure or any changes in the patient's condition if a staff member feels the patient's condition is deteriorating.
Review of facility policy entitled "Cervical Ripening" identified that the balloon catheter may be expelled when cervical dilation occurs, however, the balloon catheter must be removed no longer than 12 hours after insertion.
Review of the Certified Nurse Midwife (CNM) privileges identified that the CNM will manage the care of normal newborns and women, antepartally, intraparatally and postpartally. Further review indicated that the CNM will care for patients of the practice according to agreed upon protocols and in consultation with the physician.
Review of hospital perinatal risk assessment conducted on 12/13-12/14/17 and received on 12/27/17 identified that the obstetrical department had no clear guidelines for on-call providers related to active labor, high risk oversight of Certified Nurse Midwife (CNM) or other elective surgeries. In addition, the assessment indicated that there were no specific written guidelines that outline what conditions for which either the CNM or Family Medicine Specialists need to consult, co-manage or refer to obstetricians. Also, staff were unclear on the hospital wide use of rapid response process and/or codes. Further review failed to identify that the consultant's recommendations to mitigate risk regarding the roles and responsibilities of the medical staff including the medical management of active labor and/or high risk pregnancies were implemented.
Subsequent to surveyor inquiry on 3/2/18, the facility had submitted an immediate action plan to the state agency. The action plan included re-educating staff on caring for a preeclamptic patient, timely removal of a cervical balloon catheter and when to activate the rapid response team, reviewing of policies and procedures pertaining to family birthing and reviewing the roles and responsibilities of the medical and family birthing staff.
Subsequent to surveyor inquiry on 3/2/18, the facility had submitted an immediate action plan to the state agency. The action plan included re-educating staff on caring for a preeclamptic patient, timely removal of a cervical balloon catheter and when to activate the rapid response team, reviewing of policies and procedures pertaining to family birthing and reviewing the roles and responsibilities of the medical and family birthing staff.

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3. *Based on a review of staffing schedules, review of the staffing plan, review of facility documentation and interviews, the facility failed to ensure that the planned staff to patient ratio was maintained in the ICU (intensive care unit). The finding includes:
   a. Review of ICU staffing, staffing plan, patient acuity and patient for the dates of 2/10/18, 2/11/18 and 2/16/18 through 3/2/18. The ICU patient census and/or staffing at the start of the evening shift on 2/10/18 was 20 patients, 5 RNs, 2 NAs and identified that 1 RN cared for 4 ICU level patients for the greater part of the evening shift. Two patients were newly weaned from ventilators on the day shift, one patient had required a unit of packed red blood cells on the day shift and remained ICU level of care and one patient left AMA (against medical advice) before 7:00PM replaced by a newly admitted patient who required frequent monitoring. Staffing and Census for 2/10/18 into 2/11/18 on the night shift noted a census of 18 patients and NA staffing dropped from 1 to none. The Unsafe Staffing Form dated 2/10/18 and submitted by ICU staff to the Evening Supervisor identified that staff felt that the staffing was not adequate to safely address patient needs with compromises to patient basic hygiene, timely medication administration, and timely patient assessments as required. Review of the email from the evening supervisor dated 2/10/18 indicated that only four nurses were scheduled for the 7:00 PM to 7:00 AM shift, one nurse agreed to stay from 11:00 PM to 3:00 AM and the staffing sheets did not reflect the decrease to 4 nurses for 18 patients after 3:00 AM on 2/11/18. Interview with Nurse Manager #1 on 3/7/18 at 8:12 AM noted that due to nurses leaving, a decrease in ICU nurses and increased patient census in February, the ICU staffing plan could not be met on the evening shift on 2/10/18 and the night shift into 2/11/18. Further interview with the Nurse Manager #1 indicated that the decreased staffing levels were not safe. Interview with the Chief Nursing Officer on 3/8/18 at 2:20 PM indicated that 2/12/17 was the only other reported short staffed day and although calls were made to try to increase staffing on 2/10/18 and 2/11/18, attempts were unsuccessful. The hospital ICU staffing plan identified, in part, that two flex telemetry or intermediate care patients housed in the ICU unit counted as 1 ICU patient and every effort should be made not exceed a three patient assignment.

The following are violations of the State of Connecticut Public Health Code Section 19-13-D3 (b) Administration (2) and/or (d) Medical Records (3) and/or (e) Nursing Service (1) and/or (i) General (6).

4. *Based on a clinical record review, staff interviews, and a review of hospital documentation for one of six sampled obstetrical patients (Patient #1), the hospital failed to consistently document the patients output while Magnesium Sulfate was administered and/or failed to consistently document the patient's oxygen saturation and/or failed to conduct oxygen saturations every thirty minutes in the intrapartum period and/or failed to timely remove a balloon catheter utilized for cervical ripening and/or failed to initiate a rapid response when

the patient's condition had deteriorated in accordance with the hospital's policies and procedures. The findings included:

a. Review of the clinical record identified Patient #1 was admitted to the hospital on 1/16/18 at 2:43 PM. Patient #1 was thirty eight and one half weeks gestation with severe pre-eclampsia and a known fetal demise. Patient #1 was scheduled for an induction of labor. On arrival to the hospital Patient #1 was afebrile. Initial blood pressures were as follows; 160/100 mmHg and 203/132 mmHg. The clinical record indicated on 1/16/18 Patient #1's blood pressures intermittently continued to be elevated. The patient's blood pressure on 1/16/18 at 6:30 PM was 174/106 mmHg, at 7:33 PM 159/100 mmHg and at 8:50 PM the blood pressure was 167/101 mmHg. Patient #1 intermittently complained of blurred vision, headaches and right upper epigastric pain. The goal was to keep the patients' blood pressure less than 160/100 mm/hg. Hydralazine 10 milligrams (mg) and intravenous (IV) was administered on multiple occasions as a treatment modality for hypertension. Intravenous (IV) Magnesium Sulfate was administered for the prevention of seizures. Pitocin was administered via titration on 1/16/18 and on 1/18/18 for the induction on labor. On both occasions the maximum dose of 20 milliunits/minute was achieved absent progression of labor. Cervidil, Cytotex, and a balloon catheter were utilized for assistance with cervical ripening. Further review of the clinical record identified Patient #1's blood pressures continued to be elevated. On 1/18/18 at 8:31 AM the patient's blood pressure was 167/101 mmHg and at 9:28 AM the blood pressure was 161/103 mmHg. On 1/18/18 at 8:25 PM, Patient #1 became hypotensive with a blood pressure of 81/48 mmHg with a heartrate of 110 beats/minute (normal 60-100 beats/minute), and a temperature of 103 degrees Fahrenheit (normal temperature 98.6 degrees) was noted. Anesthesia was notified and arrived to the patient's room at 8:31 PM with Ephedrine and a fluid bolus being administered. MD #7 was called into the hospital by the nursing staff at 8:33 PM as the patient was managed by a certified midwife who was assisting another patient. MD #7 was at the bedside of Patient #1 at 9:20 PM (40 minutes later). Patient #1 was diagnosed with chorioamnionitis and an emergent Cesarean Section was performed. Patient #2 was delivered stillborn on 1/18/18 at 9:48 PM. Patient #1 remained hypotensive despite the administration of vasopressors. Subsequent to surgery, Patient #1 was transferred to the Intensive Care Unit for further management and was ultimately transferred to a higher level of care hospital on 1/19/18 at 3:55 AM for the treatment of sepsis, disseminated intravascular coagulation (DIC) and hemorrhagic shock. Review of the discharge summary from the transferring hospital identified on 1/19/18 at 7:00 AM the patient went into PEA arrest (Pulseless electrical activity) and cardiopulmonary resuscitation was performed. Patient #1 was pronounced deceased on 1/19/18 at 8:25 AM. Review of the autopsy report identified the cause of death as severe preeclampsia leading to intrauterine fetal demise, leading to a cesarean section complicated by septic shock with disseminated intravascular coagulation.

b. Review of the physician's orders identified on 1/16/18 at 6:20 PM Magnesium Sulfate 20 grams/500 ml was ordered for seizure prophylaxis with a loading dose of 4 grams and a maintenance dose of 2 grams/hour. Review of the intake and output shift record identified from 1/16/18 at 6:20 PM through 1/18/18 at 8:30 PM the urine output failed to be

documented on three occasions. Interview with Nurse Manager #2 on 3/2/18 at 1:00 PM indicated hourly urine output should have been documented and was not. The hospital policy entitled Management of Pre-eclampsia and Eclampsia directed in part, that when a patient was administered Magnesium Sulfate, the patient's output would be documented hourly.

c. Interview and review of the obstetrical pre-eclampsia assessment sheets with Nurse Manager #2 on 3/2/178 at 1:10 PM identified from 1/16/18 at 6:20 PM through 1/18/18 at 9:12 AM when the patient was in the antepartum period, oxygen saturations failed to be documented on seventeen occasions. Review of the hospital policy entitled Management of Pre-eclampsia and Eclampsia, directed in part, that when a patient was administered Magnesium Sulfate, oxygen saturations would be documented hourly in the antepartum period.

d. Interview with Nurse Manager #2 on 3/2/18 at 1:20 PM indicated the intrapartum period began for Patient #1 on 1/18/18 at 9:12 AM and commencing at that time oxygen saturations should have been conducted every thirty minutes and were not. Review of the obstetrical pre-eclampsia assessment sheets with Nurse Manager #2 identified from 1/18/18 at 9:12 AM through 1/18/18 at 8:30 PM, oxygen saturations failed to be conducted every thirty minutes on eleven occasions. Review of the hospital policy entitled Management of Pre-eclampsia and Eclampsia directed in part oxygen saturations would be documented every thirty minutes in the intrapartum period.

e. Review of the clinical record identified that a balloon catheter was inserted intravaginal on 1/17/18 at 1:23 PM and spontaneously evacuated on 1/18/18 at 9:10 AM, over nineteen hours later. Interview with the Chief of Obstetrics on 3/2/18 at 2:30 PM indicated the balloon catheter should have been removed within twelve hours due to the risk of infection. Interview with Nurse Manager #2 on 3/2/18 at 1:30 PM identified the nurses failed to have a mechanism in place to ensure the balloon catheter would be removed within twelve hours. Review of the hospital policy entitled cervical ripening failed to identify when the balloon catheter should be removed. Subsequent to the investigation, the cervical ripening policy directed the balloon catheter must be removed twelve hours or less after insertion.

f. Interview with Nurse Manager #2 on 3/2/18 at 1:40 PM indicated the nursing staff failed to activate the Rapid Response Team when the patient's condition was deteriorating on 1/18/18 at 8:25 PM. The hospital policy entitled Rapid Response Team directed the purpose of a rapid response was to prevent cardiopulmonary arrest in patients showing signs of deterioration through prompt assessment, intervention and stabilization of the patient. The team would be comprised of an intensive care nurse, a hospitalist, and a respiratory therapist. The team would include at least one member that has successfully completed training in Advanced Cardiac Life Support. The rapid response team was to assess the situation and make recommendations for the treatment and stabilization of the patient. The policy further directed that a rapid response may be activated by any staff member for any changes in the patient condition, it the staff member feels the patient's condition is deteriorating.

Further interview with Nurse Manager #2 on 3/2/18 at 1:50 PM indicated after the event on

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1/18/18 a debriefing occurred and discussion regarding the activation of a rapid response was communicated however, this discussion was not documented or provided to the entire family birthing staff members.
Interview with the Quality Manager on 3/2/18 at 1:55 PM indicated although a root cause analysis was initiated immediately following the event on 1/18/18, staff interviews had not been conducted, and a comprehensive plan had not been completed.
Subsequent to the surveyor's inquiry an immediate action plan was developed on 3/2/18 that included re-education of the family birthing center (FBC) staff regarding the care delivered in the antepartum, intrapartum, and postpartum phase of the pre-eclamptic patient. The education included a review of policies entitled; Management of Pre-eclampsia and Eclampsia, Management of Acute Hypertensive Crisis in Pregnancy, the Rapid Response Team, and a review of the high reliability organization principle of following the chain of command if needed. In addition the policy for Cervical Ripening was reviewed and revised to ensure documentation of the time when the balloon catheter was inserted, and the time of removal.

The following is a violation of the State of Connecticut Public Health Code Section 19-13-D3 (e) Nursing Service (1).

5. Based on medical record reviews, review of facility policies, observations and interviews for 1 of 3 Patients reviewed for pressure ulcers (Patient #7), the facility failed to ensure that assessment of the ulcer was complete and/or that appropriate treatment was provided. The finding includes:
   a. Patient #7 was admitted to the ICU (intensive care unit with diagnoses that included right shoulder pain. The initial nursing assessment dated 3/4/18 at 5:49 AM identified a stage II pressure ulcer to the coccyx that measured 1cm (L) by 1cm (W) and depth was left blank. The assessment further identified that the wound edges were macerated and an alginate dressing was applied. Review of the wound assessment dated 3/4/18 at 8:00 AM also documented the coccyx ulcer as 1cm by 1cm (depth left blank) and that an alginate dressing was applied. Review of wound consult sheet by Wound Ostomy Nurse #1 (RN) indicated that the Patient's coccyx ulcer measured 2.5cm by 2.5cm (depth not documented) with red wound base, slough to the upper portion of the ulcer, macerated edges and the treatment was changed to Zinc. Physician orders for wound treatment were not present in the patient's medical record. Observation on 3/6/18 at 10:12 am noted Patient #7 lying on an airflow mattress and positioned slightly to the left side. Interview with Wound Ostomy Nurse #2(RN) on 3/6/18 at 2:47 PM noted that a stage II pressure ulcer does have depth and depth should be assessed/documented. Further interview identified that the alginate dressings were used to absorb drainage and Patient #7's documentation did not reflect ulcer drainage and therefore was not an appropriate dressing/treatment. The hospital policy for wound assessment/management identified that partial thickness broken, cracked or blistered skin was considered a stage II pressure ulcer (some depth). The policy further directed to apply alginate dressings to open

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wounds with large amount of drainage.

The following are violations of the State of Connecticut Public Health Code Section 19-13-D3 (b) Administration (2).

6. Based on clinical record review, interview and policy review, for two of three patients who filed a grievance (Patient #137 and #102), the hospital failed to respond in accordance with facility policy. The findings include the following:
   a. Patient #137 presented to the Emergency Department (ED) on 10/31/16 at 8:51 AM with complaints of lower back pain that extended to the groin. Review of the clinical record failed to reflect that a pain assessment was completed upon arrival. Review of facility documentation identified that Patient #137 filed a telephone complaint with patient relations on 11/4/16 related to rude staff and failure to address pain. The patient claimed that the triage nurse was very rude, rough and lacked compassion. Interview with the VP of Quality on 5/17/18 at 2:20 PM stated the facility was unable to find any follow-up to the complaint. Interview with the Nurse Manager of the ED on 5/18/18 at 10:15 AM stated she was notified of the complaint and discussed the case with RN #21.
   Review of the facility policy directed that any statement by a patient or representative that a situation was unsatisfactory or unacceptable is considered a complaint. The policy indicated that once a complaint is filed the complainant should be contacted within 24 hours by the Manager, document the initial complaint in the RL solutions-feedback module and in part provide a follow-up response to the complainant as appropriate.
   b. Patient #102 was evaluated in the ED on 3/21/16 with complaints of vomiting. Review of facility documentation indicated on 8/9/16 a letter was sent to an outside billing agency (not employees of Hospital #1) with complaints about care received by Patient #102 in the ED and charges for services rendered on 3/21/16.
   During an interview with the Chief Compliance and Privacy Officer on 5/21/18 at 12:30 PM he/she indicated the hospital became aware of P#137's concerns on 8/22/16 and was registered as a grievance. According to the Network Chief Compliance and Privacy Officer the subsequent documentation dated 10/31/16 informed P#137 that an investigation related to P#137's concerns about the care he/she received on 3/21/16 had been completed and the results of that investigation (50 days after initial complaint filed as a grievance by the hospital).
   During an interview with the Quality Manager on 5/21/18 at 1:25 PM he/she indicated the hospital could not provide an initial response letter to P#137 in response to the grievance filed by the hospital on 8/22/16.
   The hospital Patient Complaint and Grievance policy indicated all grievances should be acknowledged, if not resolved within 7 business days but no more than 14 business days and have a 30 business day time frame for final follow-up.

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The following is a violation of the State of Connecticut Public Health Code Section 19-13-D3 (b) Administration (2) and/or (c) Medical Staff (2)(B) and/or (i) General (6).

7. *Based on medical record reviews, review of facility policies and interviews for one of three patients who had eye surgery (Patient #127), the facility failed to ensure that the correct lens implant was performed. The finding includes:
   a. Patient #127 was admitted for left phacoemulsification with intraoperative lens implant (IOL) on 3/7/18. The consent form dated 2/15/18, signed by MD #13 and Patient #127, identified left phacoemulsification with IOL. The operative record and/or operative report dated 3/7/18 noted that a "time out" was performed prior to incision and a 17.0 diopter lens was placed in the left eye. Review of MD #13's office note dated 3/8/18 indicated that, although the hospital was notified of a lens change for the Patient, the myopic lens was still inserted (in error) and Patient #127 agreed to go forward with a lens exchange. The operative report dated 3/8/18 identified that the Patient had an IOL exchange and had a 14.0 diopter lens implanted following removal of the previous lens. Interview with RN #11 on 5/17/18 at 10:13 AM noted that she pulled the lenses for all MD #13's eye cases on 3/2/18 and the lens order sheet with the change in Patient #127's lens was not present at that time. Interview with the OR Scheduler on 5/7/18 at 10:40 AM and review of the revised lens order sheet indicated that she received the changed lens order sheet on 3/2/18 at 2:24 PM and placed it backwards on the hall cork board per usual. Interview with the RN #12 (Circulator Nurse for 3/7/18) on 5/18/18 at 10:11 AM indicated that once lenses were pulled, the board was not checked for updates and the correct lens was inserted per the first lens order sheet. MD #13 was unavailable for interview at the time of the investigation. The facility Universal Protocol policy identified, in part, that a "Time Out" will be performed by the surgical team.

The following is a violation of the State of Connecticut Public Health Code Section 19-13-D3 (b) Administration (2) and/or (c) Medical Staff (2)(B) and/or (i) General (6).

8. *Based on a review of the clinical record, staff interviews and a review of facility documentation for one of one sampled patient (Patient #133), reviewed for the retention of surgical packing following an operative procedure, the facility failed to remove vaginal packing prior to discharge. The finding included:
   a. Review of the clinical record identified Patient #133 was admitted to the hospital on 2/9/18 who underwent a bilateral salpingo-oopherectomy and a TVT (tension-free vaginal tape) due to pelvic pain and a right ovarian nodule. Vaginal packing was inserted at the end of the procedure due to bleeding. Patient #133 was discharged to home on 2/10/18. Further review of the clinical record indicated Patient #133 called from home to inform the discharging unit that she removed the vaginal packing at home.
   Interview with RN #41 on 5/17/18 at 10:15 AM, who was the circulating nurse in the operating room, identified vaginal packing was not part of the operative count. RN #41 indicated she does not recall if vaginal packing was inserted or if that information was

communicated to her.
Interview with MD #41 on 5/17/18 at 11:55 AM, who was the surgeon, indicated she should have written an order to remove the vaginal packing immediately following the operative procedure and did not.
Interview with Quality Manager #2 identified it was the responsibility of the surgeon to write an order to remove the packing prior to discharge. Subsequent to the event an operating room report checklist was developed that in part included the presence or absence of packing.

The following is a violation of the State of Connecticut Public Health Code Section 19-13-D3 (c) Medical Staff (2)(B) and/or (e) Nursing Service and/or (i) General (6).

9. Based on interview and a review of the hospital's policy and procedure for the administration of Nitrous Oxide, the policy failed to indicate a dose, frequency or duration for the administration of Nitrous Oxide. The finding included:
   a. Review of the Nitrous Oxide Policy and interview with Nurse Manager #2 on 5/14/18 at 10:20 AM identified Nitrous Oxide would be inhaled as a 50-50 blend of Oxygen and Nitrous Oxide however, the policy failed to identify a dose, frequency or duration of administration and should have.

The following is a violation of the State of Connecticut Public Health Code Section 19-13-D3 (b) Administration (2) and/or (c) Medical Staff (2)(B) and/or (e) Nursing Service (1) and/or (i) General (6).

10. *Based on a review of clinical records, staff interviews and a review of hospital documentation for one of two mother/infant dyads reviewed in the intrapartum stage of labor (Patient # 134 and #134A), the hospital failed to accurately assess a non-reassuring fetal tracing and subsequently implement interventions timely to promote the highest level of well-being. The finding included:
    a. Review of the clinical record identified Patient #134 was admitted to the hospital on 8/11/16 at 11:25 PM who presented in labor at thirty eight weeks gestation. Interview and review of the fetal tracing with the Chief of Obstetrics on 5/22/18 at 4:30 PM from 11:25 PM through 11:58 PM identified moderate variability (variability is defined as fluctuations in the fetal heart rate and is an indicator of a normal functioning central nervous system). On 8/12/16 at 12:15 AM minimal variability (persistent minimal or absent fetal heart rate (FHR) variability is a sign of fetal compromise), was present absent accelerations of the fetal heart rate, (a fetal heart acceleration is an increase in the FHR greater or equal to ten beats per minute above the baseline with a duration of ten seconds or more from the most recently calculated baseline accelerations and is considered a sign of fetal well-being) until 12:59 AM. Ten liters of oxygen via a non-rebreather was administered to Patient #134 at this time. Further interview and review of the clinical record with the Chief of Obstetrics indicated at 1:09 AM and 1:10 AM possible late decelerations (late decelerations indicates an increased risk of fetal

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acidosis secondary to utero-placental insufficiency) occurred. From 1:10 AM through 2:01 AM minimal variability continued without FHR accelerations. At 1:55 AM a position change to high fowlers was made. A popsicle and juice was provided at 1:20 AM and 1:30 AM respectively. Late decelerations recurred at 2:02 AM and 2:05 AM. From 2:06 AM through 2:28 AM the tracing continued with minimal variability and lacked accelerations. At 2:29 AM MD #43 and (Nurse Midwife) NM #5 had reviewed the fetal tracing at the nurse's station. At 2:32 AM a late deceleration was identified. At 2:43 AM a bolus of intravenous fluid was administered. Minimal variability and absent accelerations continued from 2:33 AM through 3:48 AM despite resuscitative interventions. An epidural was administered at 3:24 AM. Late decelerations were noted at 3:49 AM, 3:53 AM and 4:00 AM. The fetal tracing from 4:01 AM through 5:02 AM continued with absent accelerations and minimal variability. At 5:03 AM the baseline FHR decreased from 140 beats per minute to 120 beats per minute. At 5:12 AM, a prolonged deceleration to 60 beats per minute was identified. At 5:20 AM, MD #43 performed a vaginal exam, ruptured membranes and applied an internal fetal electrode that verified the FHR of 60 beats/minute. Thick dark meconium fluid was noted. Patient #134 was taken to the operating room at 5:24 AM for a stat Caesarean Section. Patient #134A was delivered at 5:36 AM with apgar scores of 0, 0, and 4. Positive pressure ventilation was immediately administered and Patient #134A was intubated at 2 minutes of life. Chest compressions were initiated and Epinephrine was administered via the endotracheal tube with a heartrate above 60 beats/minute at 8 minutes of life. Patient #134A was transferred to the neonatal intensive care unit with an initial PH of 6.89. (Normal value 7.35-7.45). The neurological examination revealed abnormal reflexes, minimally reactive pupils, central hypotonia with extremity hypertonia and generalized clonus. The clinical impression was that of severe neonatal encephalopathy and a concern for long term neurologic impairment was prognosticated. Patient #134A was transferred to an alternate acute care facility for therapeutic hypothermia.

Review of the transferring hospital documentation identified hypothermia was induced for 72 hours with subsequent warming. Patient #134A required vasopressors for support and was extubated on 8/16/16. A percutaneous gastrostomy tube was surgically placed on 9/6/16 for continuous feedings. Hypoxic-ischemic encephalopathy stage three was diagnosed with probable electrographic seizures and a poor clinical outcome. Multiple consultations were obtained throughout hospitalization and several outpatient providers were recommended at the time of discharge and included a home health agency, surgery, neurology, ophthalmology, pediatric services and birth to three.

Further interview and review of the fetal tracing with the Chief of Obstetrics on 5/22/18 at 4:30 PM identified the first half hour of the fetal tracing was not concerning as moderate variability with fetal accelerations were identified however, after the first half hour, minimal variability, absent accelerations and a contraction pattern that was intermittently indeterminate ensued. At 1:09 AM, 1:10 AM, 2:02 AM and 2:05 AM late decelerations were present despite several resuscitative interventions. The Chief of Obstetrics indicated the standard of care would have been to perform a Cesarean Section

THE FOLLOWING VIOLATION(S) OF THE REGULATIONS OF CONNECTICUT STATE AGENCIES AND/OR CONNECTICUT GENERAL STATUTES WERE IDENTIFIED

at approximately 2:00 AM, after two hours of resuscitative interventions did not improve the fetal tracing.
Subsequent to the surveyors inquiry an immediate plan of correction dated 5/23/18 directed in part that the medical staff would be educated in the management of fetal monitoring. Mandatory education would be provided as part of continuing education. In addition, immediate education would be provided by one to one mentoring in the management of electronic fetal monitoring to the providers that were involved in the case, by the Department Chair or designee until formal education was provided.

The following are violations of the State of Connecticut Public Health Code Section 19-13-D3 (e) Nursing Service (1).

11. Based on a review of clinical records, interview and policy review, for two of three patients reviewed for pain (Patient #136 and #137), the hospital failed to ensure the patient's pain was assessed and/or reassessed following the administration of medication in accordance with facility policy. The findings include the following:
    a. Patient #136 presented to the Emergency Department (ED) on 3/18/17 at 8:14 PM with complaints of weakness and being dizzy for several weeks. Review of the physician note dated 3/18/17 at 10:48 PM indicated that the patient's symptoms were moderate to severe and worse when standing. The record reflected that intravenous fluids were administered and that an "ambulatory trial" was completed however the patient felt that he/she was not able to go home. A nurse's note dated 3/19/17 at 12:00 AM identified that the patient complained of back pain and that Tylenol 1000 milligrams (mg) was administered at 1:20 AM. The record failed to reflect an assessment of the patient's level of pain and/or a reassessment of the patient's level of pain to determine if the Tylenol was effective.
    Review of the facility policy indicated that the patients will have their level of pain reassessed after medication administration or an intervention provided to relieve pain.
    b. Patient #137 presented to the ED on 10/31/16 at 8:51 AM with complaints of lower back pain that extended to the groin. Review of the clinical record with the Nurse Manger on 5/18/18 at 10:15 AM failed to reflect that a pain assessment was completed on arrival. The record indicated that Dilaudid 1 mg and Toradol 30 mg intravenously were administered at approximately 9:30 AM although there was no pain assessment documented.

The following is a violation of the State of Connecticut Public Health Code Section 19-13-D3 (e) Nursing Service (1) and/or (i) General (6).

12. *Based on a review of the clinical record, staff interviews and a review of facility documentation for one of three sampled patients reviewed for infant falls (Patient #132), the facility failed to observe the mother infant dyad hourly in accordance with the hospital policy. The finding included:

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a. Review of the clinical record identified Patient #131 was admitted to the hospital on 6/16/17 at forty one weeks gestation for an induction of labor. Patient #132 was delivered via a spontaneous vaginal delivery on 6/16/17 at 2:11 PM. On 6/17/17, at 11:45 PM Patient #131 received Tylenol for pain and a comprehensive reassessment was completed on 6/18/17 at 12:45 AM. On 6/18/17 at 3:45 AM, Patient #131 called for a nurse and indicated she was awakened by her infant crying. The infant was found on the floor of the patient's room. The patient's bed was noted to be in the high position (3.5 feet), when the nursing staff entered the room. Patient #131 indicated she last fed the baby at 2:00 AM. Patient #131 was transferred to the nursery for an examination and observation. An immediate assessment did not identify trauma or neurological abnormalities. On 6/18/17 at 5:00 AM, Patient #131 experienced central apneic episodes with oxygen desaturation that required vigorous stimulation to recover. At 7:30 AM, Patient #131 was transferred to an alternate hospital for a higher level of care.
Interview and review of the clinical record on 5/17/18 at 10:30 AM with RN #42, who was the patient's nurse, identified the last time a staff member was in the room was on 6/18/17 at 12:45 AM, three hours before the infant fell. Although the patient indicated she feed the infant at 2:00 AM that was a verbal report provided by the patient and not a direct observation.
Interview with RN #43 on 5/17/18 at 11:55 AM, who was a staff nurse on duty indicated she does not recall the time or if the infant was in the arms of the patient but does recall she informed Patient #131 that the hospital bed needed to be in the lowest position. RN #43 lowered the patient's bed at some point during the night shift.
Interview and review of the clinical record with Nurse Manager #2 on 5/17/18 at 2:30 PM failed to identify that the staff had conducted hourly rounds. Nurse Manager #2 indicated it was the expectation to visually observe the mother and infant dyad hourly.
Review of the transferring hospital discharge summary identified Patient #132's imaging revealed a small subarachnoid hemorrhage overlying the left frontal-parietal area. Neurosurgery was consulted and not further workup was recommended. Patient #132 was discharged to home on 6/25/17.
The hospital policy entitled Newborn Fall Prevention and Management directed in part that at any time that adult caretaker(s) plan to sleep or feel that they are close to falling asleep, the infant must be in a crib for safety. The policy further directed that staff members would open doors to patient rooms at least hourly, identify self, and ensure that if the infant is in arms, the adult holding him/her is not asleep or does not appear sleepy. If both mother and infant are asleep in their respective beds, they would be visualized and not disturbed.

The following is a violation of the State of Connecticut Public Health Code Section 19-13-D3 (c) Medical Staff (2)(B) and/or (e) Nursing Service (1) and/or (i) General (6).

13. *Based on a review of clinical records, staff interviews and a review of hospital documentation for one of two mother/infant dyads reviewed in the intrapartum stage of

labor (Patient # 134 and #134A), the hospital failed to accurately assess a non-reassuring fetal tracing and subsequently implement interventions timely to promote the highest level of well-being. The finding included:

a. Review of the clinical record identified Patient #134 was admitted to the hospital on 8/11/16 at 11:25 PM who presented in labor at thirty eight weeks gestation. Interview and review of the fetal tracing with the Chief of Obstetrics on 5/22/18 at 4:30 PM from 11:25 PM through 11:58 PM identified moderate variability (variability is defined as fluctuations in the fetal heart rate and is an indicator of a normal functioning central nervous system). On 8/12/16 at 12:15 AM minimal variability (persistent minimal or absent fetal heart rate (FHR) variability is a sign of fetal compromise), was present absent accelerations of the fetal heart rate, (a fetal heart acceleration is an increase in the FHR greater or equal to ten beats per minute above the baseline with a duration of ten seconds or more from the most recently calculated baseline accelerations and is considered a sign of fetal well-being) until 12:59 AM. Ten liters of oxygen via a non-rebreather was administered to Patient #134 at this time. Further interview and review of the clinical record with the Chief of Obstetrics indicated at 1:09 AM and 1:10 AM possible late decelerations (late decelerations indicates an increased risk of fetal acidosis secondary to utero-placental insufficiency) occurred. From 1:10 AM through 2:01 AM minimal variability continued without FHR accelerations. At 1:55 AM, a position change to high fowlers was made. A popsicle and juice was provided at 1:20 AM and 1:30 AM respectively. Late decelerations recurred at 2:02 AM and 2:05 AM. From 2:06 AM through 2:28 AM the tracing continued with minimal variability and lacked accelerations. At 2:29 AM, MD #43 and (Nurse Manager) NM #5 had reviewed the fetal tracing at the nurse's station. At 2:32 AM, a late deceleration was identified. At 2:43 AM, a bolus of intravenous fluid was administered. Minimal variability and absent accelerations continued from 2:33 AM through 3:48 AM despite resuscitative interventions. An epidural was administered at 3:24 AM. Late decelerations were noted at 3:49 AM, 3:53 AM and 4:00 AM. The fetal tracing from 4:01 AM through 5:02 AM continued with absent accelerations and minimal variability. At 5:03 AM, the baseline FHR decreased from 140 beats per minute to 120 beats per minute. At 5:12 AM, a prolonged deceleration to 60 beats per minute was identified. At 5:20 AM, MD #43 performed a vaginal exam, ruptured membranes and applied an internal fetal electrode that verified the FHR of 60 beats/minute. Thick dark meconium fluid was noted. Patient #134 was taken to the operating room at 5:24 AM for a stat Caesarean Section. Patient #134A was delivered at 5:36 AM with apgar scores of 0, 0, and 4. Positive pressure ventilation was immediately administered and Patient #134A was intubated at 2 minutes of life. Chest compressions were initiated and Epinephrine was administered via the endotracheal tube with a heartrate above 60 beats/minute at 8 minutes of life. Patient #134A was transferred to the neonatal intensive care unit with an initial PH of 6.89. (Normal value 7.35-7.45). The neurological examination revealed abnormal reflexes, minimally reactive pupils, central hypotonia with extremity hypertonia and generalized clonus. The clinical impression was that of severe neonatal encephalopathy and a

concern for long term neurologic impairment was prognosticated. Patient #134A was transferred to an alternate acute care facility for therapeutic hypothermia.
Review of the transferring hospital documentation identified hypothermia was induced for 72 hours with subsequent warming. Patient #134A required vasopressors for support and was extubated on 8/16/16. A percutaneous gastrostomy tube was surgically placed on 9/6/16 for continuous feedings. Hypoxic-ischemic encephalopathy stage three was diagnosed with probable electrographic seizures and a poor clinical outcome. Multiple consultations were obtained throughout hospitalization and several outpatient providers were recommended at the time of discharge and included a home health agency, surgery, neurology, ophthalmology, pediatric services and birth to three.
Further interview and review of the fetal tracing with the Chief of Obstetrics on 5/22/18 at 4:30 PM identified the first half hour of the fetal tracing was not concerning as moderate variability with fetal accelerations were identified however, after the first half hour, minimal variability, absent accelerations and a contraction pattern that was intermittently indeterminate ensued. At 1:09 AM, 1:10 AM, 2:02 AM and 2:05 AM late decelerations were present despite several resuscitative interventions. The Chief of Obstetrics indicated the standard of care would have been to perform a Cesarean Section at approximately 2:00 AM, after two hours of resuscitative interventions did not improve the fetal tracing.
Interview with RN #45 on 5/22/18 at 11:30 AM indicated that she documented moderate variability and the presence of accelerations intermittently in the clinical record when today she would have identified the variability as minimal and lacking accelerations. RN #45 also indicated she did not recognize the late decelerations in the fetal tracing. RN #45 identified at the time of this case she had been a labor and delivery nurse for less than a year and that the lack of experience was likely why she did not interpret the tracing correctly. RN #45 indicated the providers were present during labor and she relied on the practitioners who were present to intervene if needed.
Interview with Nurse Manager #2 on 6/6/18 at 10:50 AM identified RN #45 should have been able to identify the abnormal fetal tracing. Subsequent to the surveyors investigation RN #45 was provided individual training on abnormal fetal tracings.
Further interview with Nurse Manager #2 indicated although the hospital policy entitled Fetal Monitoring and Interpretation defined terminology for the assessment of fetal tracings it failed to direct interventions and a reporting mechanism when fetal tracings were abnormal or concerning.
Subsequent to the surveyors inquiry an immediate plan of correction dated 5/23/18 directed in part that the nurse involved in the case would be mentored by the nurse educator in the assessment and recognition of abnormal fetal tracings. In addition, all nursing staff would be obtaining certification in the interpretation of fetal monitoring over the next eighteen months

DATE(S) OF VISIT: June 6, 2018

THE FOLLOWING VIOLATION(S) OF THE REGULATIONS OF CONNECTICUT STATE AGENCIES AND/OR CONNECTICUT GENERAL STATUTES WERE IDENTIFIED

The following are violations of the State of Connecticut Public Health Code Section 19-13-D3 (d) Medical Records (3) and/or (e) Nursing Service (1).

14. Based on a review of clinical records, interview and policy review, for two of three patients reviewed in the outpatient behavioral health clinic (#147 and #149), the hospital failed to ensure that the treatment plans were updated in accordance with facility policy. The findings include the following:
    a. Patient #147 presented to the facility on 4/26/18. The clinical record indicated that the patient was evaluated, a treatment plan was completed and the patient was placed in the partial hospital program. The 5/14/18 physician re-evaluation recommended that the patient be admitted to the intensive outpatient program (IOP). The patient started in the IOP on 5/15/18 and a weekly case review was completed on 5/18/18. Review of the record with the Program Director on 5/24/18 failed to reflect that the treatment plan was updated when the patient's level of care had been changed.
    b. Review of Patient #149's clinical record indicated that in April of 2017 the patient had been in the IOP and was transitioned to outpatient care. The clinical record indicated that on 5/15/18 the patient requested IOP secondary to the reemergence of suicidal ideation. The patient restarted IOP on 5/15/18 however review of the record with the Program Director on 5/24/18 failed to reflect that a treatment plan was completed. Review of the treatment plan policy indicated that treatment plans are to be updated every thirty days for PHP/IOP patients or as the level of care changes.

The following is a violation of the State of Connecticut Public Health Code Section 19-13-D3 (e) Nursing Service (1) and/or (i) General (6).

15. Based on medical record review, review of facility policies and interviews for one of three patients who was administered a medication that required titration (Patient #143), the facility failed to ensure that patient assessments were completed as per facility policy. The finding includes:
    a. Patient #143 was admitted to the ICU (intensive care unit) on 5/14/18 with possible overdose and required mechanical ventilation. Review of physician orders dated 5/15/18 at 6:00 PM directed Propofol 1000mg/100ml with an initial rate of 5mcg/kg/min. The order further directed to titrate by 5mcg/kg every 5 minutes to achieve a SAS (sedation/agitation scale) of 0 to -1. Review of the Propofol infusion rates and hourly SAS on 5/17/18 at 12:54 PM identified that the documentation was lacking on 5/16/18 at 12:00 AM, 1:00 AM, 7:00 AM, 3:00 PM and 11:00 PM. In addition, documentation of the hourly Propofol drip rate and SAS were not documented for the entire night shift on 5/17/18 from 12:00 AM to 7:00 AM. Interview with the ICU Manager on 5/17/18 at 1:27 PM indicated that hourly documentation of the Propofol infusion and SAS was required in the ICU. The ICU Manager further identified that the RNs would document the missing data and, per policy, nurses had 24 hours to add an addendum to the record. Although the documenting corrections and addenda policy

identified that addenda are documented in the legally accepted method no greater than 24 hours, the Propofol policy identified that documentation included the rate and a SAS every hour.

The following is a violation of the State of Connecticut Public Health Code Section 19-13-D3 (c) Medical Staff (2)(B).

16. Based on a review of the clinical record, staff interviews and a review of the hospital policy for one sampled patient reviewed for the administration of Nitrous Oxide (Patient #117), the facility failed to ensure a telephone order was sign timely in accordance with the hospital policy. The finding included:
    a. Review of the clinical record identified Patient #117 was admitted to the hospital on 5/2/18 in labor. Physician's orders directed the use of Nitrous Oxide for analgesia. Interview and review of the clinical record with Nurse Manager #2 on 5/14/18 at 10:00 AM indicated the order was received by a nurse via a telephone order on 5/2/18 at 11:36 PM. The physician failed to sign the order until 5/7/18 at 10:44 AM. Further interview with Nurse Manager #2 indicated the order should have been signed on the same day in was entered and was not. The hospital policy entitled Medical Orders directed in part that a registered nurse can accept and document telephone or verbal orders from a practitioner. All telephone or verbal orders should be entered in the patient's medical record immediately, reviewed, and countersigned by the prescriber as soon as possible.

The following is a violation of the State of Connecticut Public Health Code Section 19-13-D3 (d) Medical Records (3) and/or (e) Nursing Service (1).

17. Based on medical record reviews, review of facility policies and interviews for one of three patients who had a blood transfusion (Patient #114), the facility failed to ensure that transfusion documentation was accurately recorded. The finding includes:
    a. Patient #114 was admitted to the ambulatory infusion area for a blood transfusion on 5/15/18. Observations on 5/15/18 at 11:23 AM noted Patient #114 in the chair with one unit of blood infusing. The transfusion record dated 5/18/18 identified that the blood was initiated at 11:10 AM. The record also noted that although the signature of the Transfusionist was present, the second signature of the verifying individual was left blank. Interview with RN #14 on 5/15/18 at 11:26 AM noted that she verified the blood for patient #114 prior to infusion initiation and forgot to sign the transfusion record. The facility policy for transfusion therapy identified that both verifying staff must sign their names on the infusion therapy paper.

DATE(S) OF VISIT: June 6, 2018

THE FOLLOWING VIOLATION(S) OF THE REGULATIONS OF CONNECTICUT STATE AGENCIES AND/OR CONNECTICUT GENERAL STATUTES WERE IDENTIFIED

The following is a violation of the State of Connecticut Public Health Code Section 19-13-D3 (b) Administration (2).

18. Based on observation of the Radiology Department, staff interviews and a review of the facility documentation, the hospital failed to ensure an acceptable level of safety and quality. The finding included:
    a. On 5/14/18 at 2:00 PM a tour of the Magnetic Resonance Imaging (MRI) area identified multiple needles were stored in a cabinet that was left unlocked. This area was not in direct observation of a staff member. Interview with the Clinical Quality Educator of Radiology on 5/14/18 at 2:05 PM indicated the cabinet should have been secured and was not. Subsequent to surveyor inquiry, the Clinical Quality Educator of Radiology locked the cabinet.

The following are violations of the State of Connecticut Public Health Code Section 19-13-D3 (f) Diagnostic and therapeutic facilities and/or (i) General (6).

19. Based on clinical inspection of radiological services, the hospital failed to ensure that safety precautions were maintained. The findings include:
    a. In accordance with Section 19-24-7 Surveys:
    (A) (1.) As used in section 19-24-1-19-24-14 inclusive "survey" means an evaluation of the radiation hazards incident to the receipt, transfer, possession, manufacture, storage, use, operation, handling, transportation or disposal of radioactive materials or other sources of radiation under a specific set of conditions. Where appropriate, such evaluation shall include a physical survey of the location of materials and equipment and measurements of levels of radiation or concentrations of radioactive material present.
    (2.) Each owner of an installation shall make or cause to be made such surveys as may be necessary to comply with sections 19-24-1 through 19-24-14 inclusive.
    (3.) The adequacy of surveys shall be subject to the review of the department's representatives.
    (B.) Each owner shall maintain records showing the results of the surveys.
    Contrary to these requirements, surveys in the lung perfusion study room failed to adequately evaluate radiological hazards associated with Xe-133. Specifically:
    " The Victoreen instrument utilized to measure Xe-133 gas radioactivity was not maintained within manufacturer's guidance for calibration. Manufacturer guidance requires annual calibration. Calibration records showed that the instrument was last calibrated over one year ago (by Manchester Hospital maintenance staff).
    " Failure to maintain gas intake flow port filter resulted in excessive filter loading that prevented proper survey of radiation concentrations. DEEP personnel identified to Manchester Hospital Staff that the manufacturer label near the flow intake port states "clean filter weekly". Filter loading level buildup indicating that this maintenance was not performed weekly. Measurements of Xe-133 are not representative of maximum concentrations. Xe-133 gas is heavier than air. The instrument is placed at a breathing

zone level to conduct surveys. The instrument should be placed in a location more indicative of a true measurement of the maximum airborne concentrations in the room (near floor).
Observations:
1.) Information/calculations concerning airborne concentrations of radioactive material are still listed in Maximum Permissible Concentrations (MPC's). MPC's were replaced by Derived Airborne Concentration values in the early 1990's.
2.) Annual Audit- 10 CFR 20, Section 20.1101 "Radiation Protection Program" subpart (C) states: "The license shall periodically (at least annually) review the radiation protection program content and implementation." The only audit the program performs is a quarterly audit, which does not meet the requirements of this section. It was pointed out to Manchester Memorial staff that they should utilize NRC NUREG 1556 Volume 9, Specific Guidance for Medical Licensees, Appendix L, "Annual Program Audit" as a guide for his annual program audit.

The following is a violation of the State of Connecticut Public Health Code Section 19-13-D3 (e) Nursing Service (1) and/or (i) General (6) and/or (l) Infection Control.

20. Based on a tour of the surgical department, review of facility policies, observations and interview, the facility failed to ensure proper hair coverage in the restricted surgical suites. The finding includes:
    a. A tour of the surgical department was conducted with the Director of Perioperative Services on 5/15/18. Observations at 9:44 AM identified the ST (surgical technician) and the physician in OR #6 with bouffant hair covering on and hair not completely contained in the hair covering. Observations at 9:48 AM of OR #7 and/or 9:49 AM of OR #5 (both during total joint cases) and/or 9:55 AM of OR #1 identified the Anesthesia Provider and/or the Patient Care Assistant and/or the Physician's Assistant with beard and/or sideburns exposed. Observations at 9:51 AM noted the surgeon, during the surgical procedure, had donned a bouffant hair covering and hair was exposed at the nape of the neck.
    Interview with the Director of Perioperative Services on 5/15/18 at 9:46 AM indicated that the surgical area follows the standards of AORN (Association of Peri Operative Registered Nurses) and all hair must be enclosed. The facility policy for surgical attire identified that all head and facial hair will be covered by an approved disposable or reusable hat/hood in restricted and semi- restricted areas.

The following is a violation of the State of Connecticut Public Health Code Section 19-13-D3 (e) Nursing Service (1) and/or (i) General (6) and/or (l) Infection Control.

21. Based on medical record reviews, review of facility policies, observations and interviews the facility failed to ensure appropriate glove changes and/or hand sanitization during patient care. The finding includes:

THE FOLLOWING VIOLATION(S) OF THE REGULATIONS OF CONNECTICUT STATE AGENCIES AND/OR CONNECTICUT GENERAL STATUTES WERE IDENTIFIED

a. A tour of the wound center was conducted on 5/16/18 with the Program Director and Patient #119's dressing change was observed at 10:02 AM. The observation identified that RN #15 removed her gloves after using a gloved hand to open a drawer and donned clean gloves without the benefit of sanitizing hands. She then proceeded to dress the Patient's wound. Interview with RN #15 on 5/16/18 at 10:20 AM indicated that she was nervous. The facility handwashing policy identified to sanitize hands after glove removal.

The following are violations of the State of Connecticut Public Health Code Section 19-13-D3 (e) Nursing Service (1) and/or (i) General (6).

22. Based on observation during tour, the facility failed to ensure supplies that were ready for use had not expired and/or the environment was maintained in a sanitary manner. The findings include the following:
    a. During a tour of the Geri psychiatric unit on 5/16/18 at 10:30 AM, culture swabs stored in the supply room were observed with expiration dates in 10/2010, 10/2013, 3/16, 11/2016 and 2/2017.
    b. In addition, staple remover kits expired in 7/2015 and 3/2017, steri-strips expired in 7/2017 and glucose control solution expired in 11/2017.
    c. Tour of the Adolescent psychiatric unit on 5/16/18 at 9:30 AM identified balls of dust hanging off the observation mirror and the door frame to the nursing area had peeling paint.

The following is a violation of the State of Connecticut Public Health Code Section 19-13-D3 (g) Pharmacy (2) and/or (l) Infection Control.

23. Based on a review of Hospital documentation it was identified that the hospitals Infection Control and Prevention committee did not consistently review required testing in the pharmacy compounding area. The findings include:
    a. A review of the monthly Infection Control and Prevention committee meeting minutes dated December 2015 through February 2018 failed to indicate the results of environmental monitoring of the pharmacy compounding area were monitored and/or reviewed by Infection Prevention.
    Review of Environmental testing reports from January 2016 to current identified no actionable levels of environmental samples had been identified.
    During an interview with the Vice President of Quality and Patient Excellence on 5/16/18 at 12:15 PM he/she indicated environmental testing is completed and monitored by the Director of Pharmacy however in review of Infection Control and Prevention committee meeting minutes it was identified that from January 2016 through February 2018 the environmental testing had not been report and/or reviewed by Infection Prevention.
    Interview with the Infection Prevention Nurse on 5/16/18 at 1:30 PM identified the

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results had not been discussed in the Infection Control and Prevention committee meetings. He/she indicated the lack of reporting was recently identified as an issue during a separate facility review. The Infection Prevention Nurse indicated going forward he/she would gather the data pertaining to the pharmacy compounding area and the data will become a standing agenda item at the infection prevention committee meetings. The results will be reported every 6 months or should an issue be identified. Medical Staff Bylaws indicated the purpose and duties of the infection control committee shall be responsible for surveillance of infection potentials, review and analysis.

The following is a violation of the State of Connecticut Public Health Code Section 19-13-D3 (c) Medical Staff (2)(B) and/or (d) Medical Records (3).

24. Based on medical record reviews, review of facility policies and interviews for one of six surgical patients (Patient #112), the facility failed to ensure that the anesthesia recovery assessment was performed timely. The finding includes:
    a. Patient #112 was admitted to the hospital on 5/15/18 for left eye surgery. The anesthesia record dated 5/15/18 identified that the Patient had monitored anesthesia care during the operative procedure. Review of nursing documentation dated 5/15/18 indicated that the Patient arrived in the recovery area at approximately 10:30 AM. Further review of the anesthesia record noted that the anesthesia recovery assessment by the anesthesiologist was conducted at 10:20 AM at the end of the surgical case and when the Patient was still in the OR.
    Interview with the Quality Manager on 5/15/18 at 11:11 AM indicated that the anesthesia recovery assessment should be later than the anesthesia end time and be performed when the patient was in the PACU (post anesthesia care unit). The facility policy for post-operative care identified that a post- anesthesia evaluation will be completed within 48 hours after surgery and the 48 hours begins at the point the patient is moved to the designated recovery room.

The following is a violation of the State of Connecticut Public Health Code Section 19-13-D3 (c) Medical Staff (2)(B) and/or (i) General (6).

25. *Based on clinical record review and interview, for one patient reviewed for medication errors (Patient #136), the hospital failed to ensure that an antipsychotic medication was ordered for the correct patient resulting in a medication error. The finding include the following:
    a. Patient #136 presented to the Emergency Department (ED) on 3/18/17 at 8:14 PM with complaints of weakness and being dizzy for several weeks. Review of the physician note dated 3/18/17 at 10:48 PM indicated that the patient's symptoms were moderate to severe and worse when standing. The record identified that intravenous fluids were administered and that an "ambulatory trial" was completed however the patient felt that

he/she was not able to go home. Review of a physician's order (MD #11) dated 3/18/17 at 12:56 AM directed to administer Seroquel 400 milligrams. The nursing progress note dated 3/19/17 indicated that Seroquel 400 mg was administered at 1:19 AM. A physician's order dated 3/19/17 at 1:49 AM directed that an EKG be performed for dizziness and giddiness. The EKG result identified that the patient had sinus bradycardia with a rate of 54 beats per minute. The nurse's note on 3/19/17 at 2:00 AM indicated that the patient was sleeping, answers questions appropriately and remained sluggish. The patient did not feel s/he could be discharged home and was subsequently admitted to the special observation unit at 3:09 AM.

A narrative note authored by the ED Director dated 3/20/17 at 10:35 AM identified that he met with the patient and significant other to inform them that while the patient was in the ED, s/he inadvertently had ordered and administered 400 mg of Seroquel and the patient was kept in the ICU for monitoring.

Interview with MD #10 on 5/18/18 at 9:51 AM stated on 3/18/17, MD #11 was asked by a RN to write a Seroquel order, however, the order was inadvertently ordered for Patient #136 resulting in a medication error. The patient did experience somulence and hypothermia and was admitted to the ICU as a precautionary measure.

The following is a violation of the State of Connecticut Public Health Code Section 19-13-D3 (b) Administration (2).

26. Based on clinical record review, interview and policy review, for one of four patients' reviewed for treatment planning (Patient #142), the hospital failed to ensure that a comprehensive individualized treatment plan was developed. The finding includes the following:
    a. Patient #142 was admitted on 5/4/18 after an intentional overdose with a history of borderline personality, post-traumatic stress disorder, and anxiety. Although there were notations by a representative from occupational therapy (OT) on 5/7/18 and 5/9/18 to update interventions and continue current plan, the record failed to reflect that OT completed a comprehensive evaluation. Review of the clinical record with the Nursing Director on 5/17/18 lacked evidence that a comprehensive occupational therapy (OT) evaluation was completed and/or that OT interventions were identified as part of the treatment plan. The policy indicated members of the treatment team are responsible for the discipline specific assessments. The OT assesses the patients work history, self-care abilities, leisure pursuits, and overall cognitive function within 72 hours of admission. The treatment plan specifies services and interventions needed to meet the goals and objectives derived from the assessments.

The following is a violation of the State of Connecticut Public Health Code Section 19-13-D3 (b) Administration (2) and/or (e) Nursing Service (1).

27. Based on clinical record review, interview and policy review, for one of four patients'

reviewed for implementation of the treatment plan, (Patient #141), the facility failed to ensure that the treatment plan was revised weekly in accordance with policy. The finding includes the following:

a. Patient #141 was admitted on 5/3/17 with explosive behavior with a history of traumatic brain injury and Diabetes. The clinical record indicated that the assessments were completed on 5/4/18. Review of the clinical record with the Nurse Manager on 5/18/18 at 12:00 PM indicated that the treatment team update (log) was completed on 5/15/18, 11 days after the initial plan. Interview with the Manager on 5/18/18 at 12:15 PM indicated that the treatment plans are to be updated as needed and/or at least every seven days.

Review of the treatment planning policy failed to reflect when the treatment plan should be reviewed and/or updated. The policy indicated that the treatment plan specifies the services and interventions to meet the goals and objectives.

The following is a violation of the State of Connecticut Public Health Code Section 19-13-D3 (b) Administration (2).

28. Based on clinical record review, interview and policy review, for one of four patients reviewed for assessments (Patient #142), the facility failed to ensure that an occupational therapy (OT) evaluation was completed. The finding includes the following:
    a. Review of Patient #142's clinical record on 5/17/18 with the Nursing Director indicated that the patient was admitted on 5/4/18. The clinical record indicated that the Nursing, Physician and Social Work assessments were completed on 5/4/18. The record failed to reflect that a comprehensive OT assessment was completed.

    The policy indicated members of the treatment team are responsible for the discipline specific assessments. The OT assesses the patients work history, self-care abilities, leisure pursuits and overall cognitive function within 72 hours of admission.

The following are violations of the State of Connecticut Public Health Code Section 19-13-D3 Short Term Hospitals, General and Special (a) Physical Plant (4) & (i) General (6).

29. During a tour and subsequent documentation review of the Manchester Memorial Hospital on 05/14/18 through 05/29/18, the following was observed:
    a. The surveyor was not provided with documentation Engineering Director that indicated that the deficiencies noted on the report for infrared inspection and testing of the facilities electrical panels throughout the facility identified as being high priority had been corrected.
    b. The surveyor was not provided with documentation by the Engineering Director that indicated that the deficiencies noted on 02/14/18 report for the inspection and testing of the piped in medical gas system had been corrected i.e. master alarms, manifolds, missing zone valves as required by NFPA 99.

DATE(S) OF VISIT: June 6, 2018

THE FOLLOWING VIOLATION(S) OF THE REGULATIONS OF CONNECTICUT STATE AGENCIES AND/OR CONNECTICUT GENERAL STATUTES WERE IDENTIFIED

The following is a violation of the State of Connecticut Public Health Code Section 19-13-D3 (a) Physical Plant (4) and/or (i) General (6).

30. The facility did not ensure that piped in medical gas systems are in compliance with NFPA 99, 5.1.14.2 Maintenance Programs.
On 05/29/18 at 1:00 PM, the surveyor was not provided with documentation by the Engineering Director that indicated that the deficiencies noted on 02/14/18 report for the inspection and testing of the piped in medical gas system had been corrected i.e. master alarms, manifolds, missing zone valves as required by NFPA 99.
The facility did not ensure that electrical wiring and equipment is in accordance with NFPA 70, "National Electrical Code", as required by section # 9.1.2 of the referenced, "Life Safety Code"
On 05/29/18 at 1:30 PM, the surveyor was not provided with documentation by the Engineering Director that indicated that the deficiencies noted on the report for infared inspection and testing of the facilities electrical panels throughout the facility identified as being high priorty had been corrected.

The following is a violation of the State of Connecticut Public Health Code Section 19-13-D3 (b) Administration (2) and/or (c) Medical Staff (2)(B) and/or (i) General (6).

31. Based on medical record reviews, review of facility policies and interviews for one of three patients who had surgery involving an explant (Patient #126), the facility failed to ensure that the entire explant was removed as per the surgical consent. The finding includes:
a. Patient #126 was admitted for laparoscopic band removal on 9/25/17. The consent form for 9/25/17 was signed by MD #12 and Patient #126 and identified robotic Roux- EN- Y gastric bypass and robotic removal of gastric band and port. The operative record and/or operative report dated 9/25/17 noted that the final count was correct and/or the adjustable gastric band and port were removed robotically and gastric bypass were performed by MD #12. The upper GI (gastrointestinal) series dated 9/26/17 identified that a catheter device was observed in the right upper abdomen. MD #12's progress note dated 9/26/17 indicated that the UGI noted a band in the abdominal cavity, Patient #126 was notified and band extraction surgery was planned. The operative report by MD #12 dated 9/26/17 identified that the retained lap band was removed. Interview with MD #12 on 5/17/18 at 11:08 AM indicated that per, usual, once the gastric band was removed off of the Patient's stomach, the band was "put to the side" of the Patients abdomen, the gastric bypass was performed and the band was never removed from the Patient's abdominal cavity in error. MD #12 further noted that although counts of items brought into the OR were always performed, the count never included something removed from a patient that the patient had come into the OR with (explant). The facility policy for retained surgical items identified that the surgeon will perform a methodical wound exploration when closing counts are initiated.
Subsequent to the event, the facility submitted a CAP that included revision of the

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Universal Protocol sheet to account for explants at sign off, staff education and review of the event as a safety event by the Surgical Services Leadership. The facility was found to be compliant with the plan as submitted.

The following is a violation of the State of Connecticut Public Health Code Section 19-13-D3 (i) General (6) and/or (l) Infection Control.

32. Based on a tour of the endoscopy unit, review of manufacturer's recommendations, observations and interviews the facility failed to ensure that endoscopes were properly cleaned with enzymatic solution. The finding includes:

a. A tour of the endoscopy unit was conducted with the Ambulatory Services Manager on 5/15/18. Observation of the scope reprocessing area at 11:33 AM identified a sink marked with a water "fill" line and a sign above the sink denoting that the line reflected a 4 gallon fill. Interview with the CSP (Certified Sterile Processor) on 5/15/18 at 11:33 AM indicated that she uses 2 ounces of enzymatic in the sink per the 4 gallons of water to initially clean the scopes. Observation of water added to the fill line identified that 6 gallons of water and not 4 gallons were present in the sink when water reached the fill-line marking. Review of the enzymatic manufacturer's recommendations and interview with the CSP identified that an additional ounce of enzymatic cleaner was needed when the sink was filled with water to the fill line. The manufacturer's recommendations for Acedcide enzymatic cleaner directed 1/2-1 ounce of enzymatic cleaner per gallon of water.

ECHN
Eastern Connecticut Health Network

Approved
8/16/18
SHN

Eastern Connecticut Health Network
71 Haynes Street
Manchester, CT 06040
860.533.3414
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August 15, 2018

Susan H. Newton, R.N.
Supervising Nurse Consultant
Facility Licensing and Investigations Section
State of Connecticut
Department of Public Health
410 Capitol Avenue – MS # 12HSR
P.O. Box 340308
Hartford, CT 06134

Dr. Ms. Newton.

Pursuant to the Department of Health's letter of August 14, 2018, relating to the visits made to Manchester Memorial Hospital, which concluded on June 6, 2018, a detailed Plan of Correction is attached to address the alleged violations.

The filing of this does not constitute any admission as to any of the alleged violations set forth in the statement of deficiencies. The Implementation Plan is being filed as evidence of the facility's continued compliance with all applicable laws and the facility's desire to continue to provide quality service.

Please contact Kathleen Davis, Vice President of Quality & Safety, at (860) 533-3432, with any questions or concerns.

Respectfully,

Michael Collins
Chief Executive Officer

cc: Kathleen Davis

Encl.

STATE OF CONNECTICUT
DEPARTMENT OF PUBLIC HEALTH

Raul Pino, M.D., M.P.H.
Commissioner

Dannel P. Malloy
Governor
Nancy Wyman
Lt. Governor

Healthcare Quality And Safety Branch

August 14, 2018

Michael Collins, Administrator
Manchester Memorial Hospital
71 Haynes Street
Manchester, CT 06040

Dear Mr. Collins:

This is an amended edition of the violation letter originally sent on August 7, 2018.

Unannounced visits were made to Manchester Memorial Hospital commencing on February 26, 2018 and concluding on June 6, 2018 by representatives of the Facility Licensing and Investigations Section of the Department of Public Health for the purpose of conducting multiple investigations.

Attached are the violations of the Regulations of Connecticut State Agencies and/or General Statutes of Connecticut which were noted during the course of the visits.

An office conference has been scheduled for August 22, 2018 at 10:00AM in the Facility Licensing and Investigations Section of the Department of Public Health, 410 Capitol Avenue, Second Floor, Hartford, Connecticut. Should you wish to retain legal representation, your attorney may accompany you to this meeting. Please be prepared to discuss those violations Identified with an asterisk.

You may wish to dispute the violations and you may be provided with the opportunity to be heard. If the violations are not responded to by August 8, 2018 or if a request for a meeting is not made by the stipulated date, the violations shall be deemed admitted.

Please prepare a written Plan of Correction for the above mentioned violations to be presented at this conference.

Each violation must be addressed with a prospective Plan of Correction which includes the following components:

(1) The measures that the institution intends to implement or systemic changes that the institution intends to make to prevent a recurrence of each identified issue of noncompliance;
(2) the date each such corrective measure or change by the institution is effective;
(3) the institution's plan to monitor its quality assessment and performance improvement functions to ensure that the corrective measure or systemic change is sustained; and
(4) the title of the institution's staff member that is responsible for ensuring the institution's compliance with its plan of correction.

Alternate remedies to violations identified in this letter may be discussed at the office conference. In addition, please be advised that the preparation of a Plan of Correction and/or its acceptance by the Department of Public Health does not limit the Department in terms of other legal remedies, including but not limited to, the issuance of a Statement of Charges or a Summary Suspension Order and it does not preclude resolution of this matter by means of a Consent Order.

Connecticut Department of Public Health

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410 Capitol Avenue, P.O. Box 340308
Hartford, Connecticut 06134-0308
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Affirmative Action/Equal Opportunity Employer

DATE(S) OF VISIT: June 6, 2018

THE FOLLOWING VIOLATION(S) OF THE REGULATIONS OF CONNECTICUT STATE AGENCIES AND/OR CONNECTICUT GENERAL STATUTES WERE IDENTIFIED

Should you have any questions, please do not hesitate to contact this office at (860) 509-7400.

Respectfully,

Susan Newton, RN, BS
Supervising Nurse Consultant
Facility Licensing and Investigations Section

SHN:mb

THE FOLLOWING VIOLATION(S) OF THE REGULATIONS OF CONNECTICUT STATE AGENCIES AND/OR CONNECTICUT GENERAL STATUTES WERE IDENTIFIED

The following is a violation of the State of Connecticut Public Health Code Section 19-13-D3 (b) Administration (2) and/or (c) Medical Staff (2)(B) and/or (c)(4)(A) and/or (i) General (6).

1. *Based on a review of the clinical record, staff interviews, and a review of hospital documentation for one of three patients (Patient #1), who was a high risk obstetrical patient that required an emergency cesarean section, the hospital's governing body failed to ensure that the medical staff was accountable to the governing body for the quality of care provided to the patients and/or the hospital's Quality Assurance and Performance Improvement (QAPI) failed to implement preventive actions and mechanisms subsequent to a perinatal risk assessment dated 12/27/17 to ensure patient safety. The finding includes:
   a. Patient #1 was admitted to the hospital on 1/16/18 at 2:43pm with complaints of edema, elevated blood pressure and fetal demise after being evaluated in a physician's office. On arrival, Patient #1's blood pressure was 160/100 and 203/132. Patient #1 had no visual changes, headache, temperature was 98.2 (normal range) and had no epigastric pain on admission. Patient #1 was diagnosed with preeclampsia, intrauterine fetal demise and was a high risk pregnancy. Patient #1 received Hydralazine 10mg (to reduce blood pressure) and Cervidil was placed at 5:23pm.
   Review of the clinical record from 1/16/18-1/18/18 identified that Patient #1's blood pressure's intermittently continued to be elevated with blood pressures noted on 1/16/18 at 7:33pm 159/100, 8:50pm 167/101, 630pm 174/106, the patient complained of blurred vision. The goal was to keep blood pressure less than 160/100. Patient #1 was given multiple doses of Hydralazine and Magnesium Sulfate IV was started. Further review identified that the patient was being managed by multiple certified midwives (CSM) from admission through discharge.
   On 1/17/18 at 8:30am, Pitocin IV (to induce labor) was started. On 1/17/18 at 12:30pm, the vaginal balloon catheter was inserted (for cervical dilation and ripening). Further review identified that Patient #1's blood pressures continued to be elevated on 1/18/18 at 8:31am 167/101 with complaints of blurred vision and at 1/18/18 at 9:28am 161/103.
   Further review identified that on 1/18/18 at 7:56pm, the Pitocin IV was discontinued since the patient was at the maximum dose of 20mg and labor was not progressing. Patient #1's blood pressures continued to be elevated at 8:31am 167/101 with complaints of blurred vision and at 1/18/18 at 9:28am 161/103. On 1/18/18 at 9:10am, the vaginal balloon catheter fell out (19 hours later) after insertion. Further review identified that although the MD #3 was called and made aware of the patient's condition which included an elevated blood pressure and blurred vision, the physician was not in the building managing the high risk patient and/or any OB physician in the hospital.
   Review of the clinical record identified that on 1/18/18 at 8:25pm, Patient #1 became hypotensive with a blood pressure of 81/48, tachycardia at 110 and a temperature of 103 degrees Fahrenheit. Anesthesia was called in to the room and a fluid bolus was started. The on-call obstetrician (MD #1) was called in and arrived 40 minutes later, MD #1 evaluated the patient and a diagnosis of chorioamnionitis (intra-amniotic infection) was made with a decision to perform an emergency Cesarean Section. Patient #1 delivered a stillborn on 1/18/18 at 9:48pm. Further review failed to identify that the

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Rapid Response Team was activated (team of providers that respond to hospitalized patients with early signs of deterioration) by the staff when the patient's status had deteriorated in accordance with hospital policy.
Review of the progress note dated 1/19/18 identified that MD #1 was called to the intensive care unit (ICU) by the ICU attending (MD #2) after the patient's blood pressures continued to drop. Blood pressures reported were 83/70, 56/41 and 71/38 with the patient on the maximum dose of four vasopressors (Levophed, Dopamine, Neo-Synephrine and Vasopressin drips) Patient #1 intubated, IV antibiotics and multiple doses of blood products were given. Patient #1 was presumed to be in septic shock and DIC from chorioamnionitis. Further review identified that after a discussion with the family a decision was made to transfer the patient to a higher level of care due to the patient's deteriorating condition. Patient #1 was airlifted to Hospital #2 at 3:55am. On 1/19/18, Patient #1 when into a cardiac arrest at 7:00am and expired at 8:25am.
Review of the autopsy report identified the cause of death as severe preeclampsia leading to intrauterine fetal demise, leading to a cesarean section complicated by septic shock with disseminated intravascular coagulation.
Interview with the Chief Nursing Officer on 3/7/18 identified that the hospital had an external consultant review of obstetrical services in 12/2017 identified concerns regarding medical management of high risk pregnancies.
Interview with the Chief Medical Officer on 3/7/18 identified that the physician and not a CNM should have been at the hospital to care for high risk pregnancy patients and that Patient #1 had went too long before having a C-Section. Further interview identified that the hospital was developing a protocol for fetal demise and for the management of the cervical balloon catheter for cervical ripening by the provider. MD #2 indicated that when labor is extended and when the cervical balloon catheter was left in with no staff monitoring the balloon catheter, the risk of infection increased and the Patient #1 became septic.
Interview with the Chief of Obstetrics on 3/7/18 identified that the physician would need to be at the hospital for any high risk patient. Further interview identified that balloon catheter needed to be removed after twelve hours and he/she would have performed the C-Section in the afternoon on 1/18/18 since the patient had no change in progression of labor and was at the maximum dose of Pitocin. MD #1 indicated that he/she had developed a new level system recommended from ACOG (American Colleges of Obstetricians and Gynecologist), however had not implemented it yet.
Review of facility policy entitled "Management of Preeclampsia and Eclampsia" identified that the practitioner will be notified within 30 minutes of the arrival of all gravid patients that present to the family birthing center with a blood pressure greater than 140mmHg systolic or greater than 90mmHg diastolic occurring with two readings taken at least 15 minutes apart. In addition, the practitioner will be requested at the bedside for any patient with a blood pressure greater than 160mmHg systolic or greater than 100mmHg diastolic occurring with two readings taken at least 15 minutes apart.
Review of the facility policy entitled "Rapid Response Team" identified that a staff member will consider activating the Rapid Response Team for any of the changes in a patient's condition which includes an acute change in a systolic blood pressure or any

THE FOLLOWING VIOLATION(S) OF THE REGULATIONS OF CONNECTICUT STATE AGENCIES AND/OR CONNECTICUT GENERAL STATUTES WERE IDENTIFIED

changes in the patient's condition if a staff member feels the patient's condition is deteriorating.
Review of facility policy entitled "Cervical Ripening" identified that the balloon catheter may be expelled when cervical dilation occurs, however, the balloon catheter must be removed no longer than 12 hours after insertion.
Review of the Certified Nurse Midwife (CNM) privileges identified that the CNM will manage the care of normal newborns and women, antepartally, intraparatally and postpartally. Further review indicated that the CNM will care for patients of the practice according to agreed upon protocols and in consultation with the physician.
Review of hospital perinatal risk assessment conducted on 12/13-12/14/17 and received on 12/27/17 identified that the obstetrical department had no clear guidelines for on-call providers related to active labor, high risk oversight of Certified Nurse Midwife (CNM) or other elective surgeries. In addition, the assessment indicated that there were no specific written guidelines that outline what conditions for which either the CNM or Family Medicine Specialists need to consult, co-manage or refer to obstetricians. In addition, staff were unclear on the hospital wide use of rapid response process and/or codes. Further review failed to identify that the consultant's recommendations to mitigate risk regarding the roles and responsibilities of the medical staff including the medical management of active labor and/or high risk pregnancies were implemented.
Review of the governing body bylaws identified that the operation committee of the governing body will oversee and direct all quality improvement activities of the hospital, including but not limited to assuring that there are ongoing programs to reduce medical errors and provide that all quality improvement activities are evaluated, assure that safety expectations are established, measure and assess the hospital's ongoing performance.
Interview with the Quality Manager on 3/2/18 at 1:55 PM indicated although a root cause analysis was initiated immediately following the event on 1/18/18, staff interviews had not been conducted, and a comprehensive plan had not been completed.
Subsequent to surveyor inquiry on 3/2/18, the facility had submitted an immediate action plan to the state agency. The action plan included re-educating staff on caring for a preeclamptic patient, timely removal of a cervical balloon catheter and when to activate the rapid response team, reviewing of policies and procedures pertaining to family birthing and reviewing the roles and responsibilities of the medical and family birthing staff.

Action Plan: An immediate corrective action plan (CAP) was developed and implemented on 3/2/18 which was accepted by the Department of Public Health on 3/2/18. This plan included:

1. The Family Birthing Center (FBC) staff will be immediately re-educated regarding the care delivered in the ante, intra, and post-partum phase of the pre-eclamptic patient. This education included the role and responsibility of the FBC staff while caring for the pre-eclamptic patient.

THE FOLLOWING VIOLATION(S) OF THE REGULATIONS OF CONNECTICUT STATE AGENCIES AND/OR CONNECTICUT GENERAL STATUTES WERE IDENTIFIED

a. Review of policy "Management of Pre-eclampsia and eclampsia" with attention to the frequency of vital signs and when to notify the practitioner/AHP.
b. Review of policy "Management of Acute Hypertensive Crisis in Pregnancy" with attention to frequency of vital signs following medication administration.

Person Responsible: Nurse Manager, FBC
Audit: Audit 5 records per month x3 months to ensure vital signs are appropriately monitored per patient condition.
Date of Completion: Education – 3/16/18; Audits 6/30/18

2. FBC staff will be immediately re-educated regarding the roles and responsibilities of the medical and FBC staff.
   a. Review of policy "Management of Pre-eclampsia and eclampsia" with attention to when a physician is required at the bedside.
   b. Review of policy "Management of Pre-eclampsia and eclampsia" with attention to documentation requirement of all communication with provider.

Person Responsible: Nurse Manager, FBC
Audit: Audit 5 records per month x3 months to ensure MD at bedside as appropriate and communication to provider is documented.
Date of Completion: Education – 3/16/18; Audits 6/30/18

3. FBC staff will be immediately re-educated regarding the Rapid Response process and chain of command.
   a. Review of policy "Rapid Response Team" with attention to the criteria for activating the rapid response team in response to a change in patient condition.
   b. Review of High Reliability Organization principle of following the chain of command. In the FBC the staff nurse will make escalating calls to the charge nurse, manager or shift supervisor, medical director of the department, and finally the administrator on call if needed.

Person Responsible: Nurse Manager, FBC
Date of Completion: Education – 3/16/18

4. Review and revise policy "Cervical Ripening" to ensure documentation of the time foley balloon catheter is inserted and the time removed. Time of removal to be investigated to determine evidence-based practice standard in accordance with manufacturer's recommendation. In the interim, it will be kept in no longer than 12 hours.
   Person Responsible: Nurse Manager, FBC
   Audit: Audit 5 records per month x3 months to ensure prompt removal of balloon catheter.
   Date of Completion: Education – 3/16/18; Audits 7/31/18

THE FOLLOWING VIOLATION(S) OF THE REGULATIONS OF CONNECTICUT STATE AGENCIES AND/OR CONNECTICUT GENERAL STATUTES WERE IDENTIFIED

Action Plan:

1. An emergency meeting of the Department of OB/GYN was held on 3/8/18 to discuss the proposed Levels of Care guidelines drafted by the Department Chair. Senior Leadership was present at this meeting. The CEO reported that we were notified today that we were in Immediate Jeopardy by CMS. He also educated/reinforced to all providers and CNMs present that the scope of hospital privileges for all CNMs must be limited to management of care of the normal newborn and women as set forth in the privileges agreements. This is a temporary measure until a more clearly defined scope is developed and approved and changes made to the privileges document to coincide with the levels of care. It was stated that the scope of practice that the CNMs must abide by at this time is consistent with the provision of care listed in the Level A of the proposed guidelines which reflect the normal newborn and pregnant woman. Effective 3/8/18 levels of care beyond normal pregnancy as defined in Level A must be managed by a physician.

2. A memo to this effect was sent overnight delivery to all OB practitioners/CNMs on 3/9/18

3. An emergency meeting of the Medical Executive Committee (MEC) with Senior Leadership attendance was held on 3/15/18 to review the proposed Levels of Care guidelines. The MEC made a recommendation to obtain opinion from external consultant and to send the proposal to the Credentials Committee.

4. An emergency meeting of the Credentials Committee with Senior Leadership attendance was held on 4/4/18 to review the proposed Levels of Care guidelines. The members recommended several changes and are awaiting the opinion of the external consultant.

5. External consultant comments/opinion received and revisions made to the proposed Levels of Care guidelines and document sent back to the Credentials Committee for review and approval at the 5/1/18 meeting.

6. Levels of Care guidelines approved at the 5/8/18 MEC.

7. Levels of Care guidelines reviewed at the 5/21/18 Department of OB/GYN meeting.

8. Levels of Care and Privileges documents were both presented to the Advisory Board and approved on 5/30/18.

Person Responsible: Chair, Department OB/GYN
Audit: 5 records per month x 3 months will be reviewed to ensure appropriate provider caring for patient based on level of care.
Date of Completion: 8/31/18

THE FOLLOWING VIOLATION(S) OF THE REGULATIONS OF CONNECTICUT STATE AGENCIES AND/OR CONNECTICUT GENERAL STATUTES WERE IDENTIFIED

9. This case has been reviewed by the Department of OB/GYN. At the time of the review it was determined that there was a need to clarify the scope of practice for the Certified Nurse Midwife in the care of all OB patients. The Department of OB/GYN is in the process of defining the role of the CNM in the management of OB patients.

Person Responsible: Chair, Department OB/GYN

The following is a violation of the State of Connecticut Public Health Code Section 19-13-D3 (b) Administration (2) and/or (c) Medical Staff (2)(B) and/or (c)(4)(A) and/or (i) General (6).

2. *Based on clinical record reviews, review of policies and procedures and interviews with facility personnel for one of six sampled patients (Patient #1), the facility failed to ensure that the medical staff were accountable for the quality of care provided to a obstetrical patient who was determined to be a high risk pregnancy.
The medical staff failed to manage and provide the quality of care to a high risk pregnant patient; failed to ensure that a vaginal balloon catheter was removed after twelve hours to reduce the risk of an infection; failed to timely implement recommendations from the perinatal risk assessment conducted in 12/2017 for patient's that present to the hospital in active labor and/or high risk pregnancy which indicated that the hospital had no clear guidelines for on-call providers related to active labor, high risk oversight of Certified Nurse Midwife (CNM) or other elective surgeries. In addition, the assessment indicated that there were no specific written guidelines that outline what conditions for which either the CNM or Family Medicine Specialists need to consult, co-manage or refer to obstetricians. Also, staff were unclear on the hospital wide use of codes; failed to ensure that a Certified Nurse Midwife (CSM) would only provide care for normal newborns and women, antepartally, intraparatally and postpartally; and failed to activate the Rapid Response Team when the patient's status deteriorated. The findings include:

a. Patient #1 was admitted to the hospital on 1/16/18 at 2:43pm with complaints of edema, elevated blood pressure and fetal demise after being evaluated in a physician's office. On arrival, Patient #1's blood pressure was 160/100 and 203/132. Patient #1 had no visual changes, headache, temperature was 98.2 (normal range) and had no epigastric pain on admission. Patient #1 was diagnosed with preeclampsia, intrauterine fetal demise and was a high risk pregnancy. Patient #1 received Hydralazine 10mg (to reduce blood pressure) and Cervidil was placed at 5:23pm.
Review of the clinical record from 1/16/18-1/18/18 identified that Patient #1's blood pressure's intermittently continued to be elevated with blood pressures noted on 1/16/18 at 7:33pm 159/100, 8:50pm 167/101, 630pm 174/106, the patient complained of blurred vision, headaches and right upper epigastric pain. The goal was to keep blood pressure less than 160/100. Patient #1 was given multiple doses of Hydralazine and Magnesium Sulfate IV was started. Further review identified that the patient was being managed by multiple certified midwives (CSM).
On 1/17/18 at 8:30am, Pitocin IV (to induce labor) was started. On 1/17/18 at 12:30pm, the vaginal balloon catheter was inserted (for cervical dilation and ripening). Further review identified that Patient #1's blood pressures continued to be elevated on 1/18/18 at 8:31am 167/101 with complaints of blurred vision and at 1/18/18 at 9:28am 161/103.
Further review identified that on 1/18/18 at 7:56pm, the Pitocin IV was discontinued since the

patient was at the maximum dose of 20mg and labor was not progressing. Patient #1's blood pressures continued to be elevated at 8:31am 167/101 with complaints of blurred vision and at 1/18/18 at 9:28am 161/103. On 1/18/18 at 9:10am, the vaginal balloon catheter fell out (19 hours later). Further review identified that although the MD #3 was called and made aware of the patient's condition, the physician was not in the building managing the high risk patient and/or any OB physician in the hospital.

Review of the clinical record identified that on 1/18/18 at 8:25pm, Patient #1 became hypotensive with a blood pressure of 81/48, tachycardia at 110 and a temperature of 103 degrees Fahrenheit. Anesthesia was called in to the room and a fluid bolus was started. The on-call obstetrician (MD #1) was called in and arrived 40 minutes later, MD #1 evaluated the patient and a diagnosis of chorioamnionitis (intra-amniotic infection) was made with a decision to perform an emergency Cesarean Section. Patient #1 delivered a stillborn on 1/18/18 at 9:48pm. Further review failed to identify that the Rapid Response Team was activated (team of providers that respond to hospitalized patients with early signs of deterioration) by the staff when the patient's status had deteriorated in accordance with hospital policy.

Review of the progress note dated 1/19/18 identified that MD #1 was called to the intensive care unit (ICU) by the ICU attending (MD #2) after the patient's blood pressures continued to drop. Blood pressures reported were 83/70, 56/41 and 71/38 with the patient on the maximum dose of four vasopressors (Levophed, Dopamine, Neo-Synephrine and Vasopressin drips) Patient #1 intubated, IV antibiotics and multiple doses of blood products were given. Patient #1 was presumed to be in septic shock and DIC from chorioamnionitis. Further review identified that after a discussion with the family a decision was made to transfer the patient to a higher level of care due to the patient's deteriorating condition. Patient #1 was airlifted to Hospital #2 at 3:55am. On 1/19/18, Patient #1 when into a cardiac arrest at 7:00am and expired at 8:25am. Review of the autopsy report identified the cause of death as severe preeclampsia leading to intrauterine fetal demise, leading to a cesarean section complicated by septic shock with disseminated intravascular coagulation.

Interview with the Chief Nursing Officer on 3/7/18 identified that the hospital had an external consultant review of obstetrical services in 12/2017 identified concerns regarding medical management of high risk pregnancies.

Interview with the Chief Medical Officer on 3/7/18 identified that the physician should have been at the hospital to care for high risk pregnancy patients and that Patient #1 had went before having a C-Section. Further interview identified that the hospital was developing a protocol for fetal demise and for the management of the cervical balloon catheter for cervical ripening by the provider. MD #2 indicated that when labor is extended and when the cervical balloon catheter was left in, the risk of infection increased and the Patient #1 became septic.

Interview with the Chief of Obstetrics on 3/7/18 identified that the physician would need to be at the hospital for any high risk patient. Further interview identified that balloon catheter needed to be removed after twelve hours and he/she would have performed the C-Section in the afternoon on 1/18/18 since the patient had no change in progression of labor and was at the maximum dose of Pitocin. MD #1 indicated that he/she had developed a new level system recommended from ACOG (American Colleges of Obstetricians and Gynecologist), however had not implemented it yet.

Although the hospital hired a consultant in 12/2017 who reviewed the medical management of high

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risk pregnancies, the consultant recommended that there was no clear guidelines for on-call providers related to active labor, high risk oversight of Certified Nurse Midwife (CNM) or other elective surgeries. In addition, the assessment indicated that there were no specific written guidelines that outline what conditions for which either the CNM or Family Medicine Specialists need to consult, co-manage or refer to obstetricians. Also, staff were unclear on the hospital wide use of codes. Further review failed to identify that any of the recommendations were implemented to mitigate the risk regarding the medical management of active labor and/or high risk pregnancies.
Review of facility policy entitled "Management of Preeclampsia and Eclampsia" identified that the practitioner will be notified within 30 minutes of the arrival of all gravid patients that present to the family birthing center with a blood pressure greater than 140mmHg systolic or greater than 90mmHg diastolic occurring with two readings taken at least 15 minutes apart. In addition, the practitioner will be requested at the bedside for any patient with a blood pressure greater than 160mmHg systolic or greater than 100mmHg diastolic occurring with two readings taken at least 15 minutes apart.
Review of the facility policy entitled "Rapid Response Team" identified that a staff member will consider activating the Rapid Response Team for any of the changes in a patient's condition which includes an acute change in a systolic blood pressure or any changes in the patient's condition if a staff member feels the patient's condition is deteriorating.
Review of facility policy entitled "Cervical Ripening" identified that the balloon catheter may be expelled when cervical dilation occurs, however, the balloon catheter must be removed no longer than 12 hours after insertion.
Review of the Certified Nurse Midwife (CNM) privileges identified that the CNM will manage the care of normal newborns and women, antepartally, intraparatally and postpartally. Further review indicated that the CNM will care for patients of the practice according to agreed upon protocols and in consultation with the physician.
Review of hospital perinatal risk assessment conducted on 12/13-12/14/17 and received on 12/27/17 identified that the obstetrical department had no clear guidelines for on-call providers related to active labor, high risk oversight of Certified Nurse Midwife (CNM) or other elective surgeries. In addition, the assessment indicated that there were no specific written guidelines that outline what conditions for which either the CNM or Family Medicine Specialists need to consult, co-manage or refer to obstetricians. Also, staff were unclear on the hospital wide use of rapid response process and/or codes. Further review failed to identify that the consultant's recommendations to mitigate risk regarding the roles and responsibilities of the medical staff including the medical management of active labor and/or high risk pregnancies were implemented.
Subsequent to surveyor inquiry on 3/2/18, the facility had submitted an immediate action plan to the state agency. The action plan included re-educating staff on caring for a preeclamptic patient, timely removal of a cervical balloon catheter and when to activate the rapid response team, reviewing of policies and procedures pertaining to family birthing and reviewing the roles and responsibilities of the medical and family birthing staff.
Subsequent to surveyor inquiry on 3/2/18, the facility had submitted an immediate action plan to the state agency. The action plan included re-educating staff on caring for a preeclamptic patient, timely removal of a cervical balloon catheter and when to activate the rapid response team, reviewing of policies and procedures pertaining to family birthing and reviewing the roles and responsibilities of the medical and family birthing staff.

THE FOLLOWING VIOLATION(S) OF THE REGULATIONS OF CONNECTICUT STATE AGENCIES AND/OR CONNECTICUT GENERAL STATUTES WERE IDENTIFIED

Action Plan: An immediate corrective action plan (CAP) was developed and implemented on 3/2/18 which was accepted by the Department of Public Health on 3/2/18. This plan included:

1. The Family Birthing Center (FBC) staff will be immediately re-educated regarding the care delivered in the ante, intra, and post-partum phase of the pre-eclamptic patient. This education included the role and responsibility of the FBC staff while caring for the pre-eclamptic patient.
   a. Review of policy "Management of Pre-eclampsia and eclampsia" with attention to the frequency of vital signs and when to notify the practitioner/AHP.
   b. Review of policy "Management of Acute Hypertensive Crisis in Pregnancy" with attention to frequency of vital signs following medication administration.

Person Responsible: Nurse Manager, FBC
Audit: Audit 5 records per month x3 months to ensure vital signs are appropriately monitored per patient condition.
Date of Completion: Education – 3/16/18; Audits 6/30/18

2. FBC staff will be immediately re-educated regarding the roles and responsibilities of the medical and FBC staff.
   a. Review of policy "Management of Pre-eclampsia and eclampsia" with attention to when a physician is required at the bedside.
   b. Review of policy "Management of Pre-eclampsia and eclampsia" with attention to documentation requirement of all communication with provider.

Person Responsible: Nurse Manager, FBC
Audit: Audit 5 records per month x3 months to ensure MD at bedside as appropriate and communication to provider is documented.
Date of Completion: Education – 3/16/18; Audits 6/30/18

3. FBC staff will be immediately re-educated regarding the Rapid Response process and chain of command.
   a. Review of policy "Rapid Response Team" with attention to the criteria for activating the rapid response team in response to a change in patient condition.
   b. Review of High Reliability Organization principle of following the chain of command. In the FBC the staff nurse will make escalating calls to the charge nurse, manager or shift supervisor, medical director of the department, and finally the administrator on call if needed.

Person Responsible: Nurse Manager, FBC
Date of Completion: Education – 3/16/18

4. Review and revise policy "Cervical Ripening" to ensure documentation of the time foley balloon catheter is inserted and the time removed. Time of removal to be investigated to determine evidence-based practice standard in accordance with manufacturer's recommendation. In the interim, it will be kept in no longer than 12 hours.

THE FOLLOWING VIOLATION(S) OF THE REGULATIONS OF CONNECTICUT STATE AGENCIES AND/OR CONNECTICUT GENERAL STATUTES WERE IDENTIFIED

Person Responsible: Nurse Manager, FBC
Audit: Audit 5 records per month x3 months to ensure prompt removal of balloon catheter.
Date of Completion: Education – 3/16/18; Audits 7/31/18

Action Plan:

1. An emergency meeting of the Department of OB/GYN was held on 3/8/18 to discuss the proposed Levels of Care guidelines drafted by the Department Chair. Senior Leadership was present at this meeting. The CEO reported that we were notified today that we were in Immediate Jeopardy by CMS. He also educated/reinforced to all providers and CNMs present that the scope of hospital privileges for all CNMs must be limited to management of care of the normal newborn and women as set forth in the privileges agreements. This is a temporary measure until a more clearly defined scope is developed and approved and changes made to the privileges document to coincide with the levels of care. It was stated that the scope of practice that the CNMs must abide by at this time is consistent with the provision of care listed in the Level A of the proposed guidelines which reflect the normal newborn and pregnant woman. Effective 3/8/18 levels of care beyond normal pregnancy as defined in Level A must be managed by a physician.

2. A memo to this effect was sent overnight delivery to all OB practitioners/CNMs on 3/9/18

3. An emergency meeting of the Medical Executive Committee (MEC) with Senior Leadership attendance was held on 3/15/18 to review the proposed Levels of Care guidelines. The MEC made a recommendation to obtain opinion from external consultant and to send the proposal to the Credentials Committee.

4. An emergency meeting of the Credentials Committee with Senior Leadership attendance was held on 4/4/18 to review the proposed Levels of Care guidelines. The members recommended several changes and are awaiting the opinion of the external consultant.

5. External consultant comments/opinion received and revisions made to the proposed Levels of Care guidelines and document sent back to the Credentials Committee for review and approval at the 5/1/18 meeting.

6. Levels of Care guidelines approved at the 5/8/18 MEC.

7. Levels of Care guidelines reviewed at the 5/21/18 Department of OB/GYN meeting.

8. Levels of Care and Privileges documents were both presented to the Advisory Board and approved on 5/30/18.

THE FOLLOWING VIOLATION(S) OF THE REGULATIONS OF CONNECTICUT STATE AGENCIES AND/OR CONNECTICUT GENERAL STATUTES WERE IDENTIFIED

Person Responsible: Chair, Department OB/GYN
Audit: 5 records per month x 3 months will be reviewed to ensure appropriate provider caring for patient based on level of care.
Date of Completion: 8/31/18

Action Plan:
1. The Risk Assessment completed by an external consultant was reviewed on 1/25/18 by Risk management, members of Senior Leadership, Family Birthing Center leadership, and Chief Medical Officer and a timeline of prioritized recommendations was developed by 4/12/18. Twice monthly follow-up meetings have been established with the Chair, Department of OB/GYN, Sr VP Patient Care Services, FBC nursing and Risk Management. Monthly follow-up meetings with Senior Leadership and FBC leadership established with priority items completed by 6/14/18.

Person Responsible: Director, Risk Management
Date of Completion: 4/12/18 and 6/14/18.

Action Plan:
1. The Risk Assessment progress updates to be reported at the Department of OB/GYN meeting on a monthly basis beginning in March 2018 until completion of action items.
2. The Levels of Care was determined to be high priority. The Chair, Department of OB/GYN began developing guidelines to mitigate the risk for patients who present with a high risk OB condition to ensure safe, quality care.

Person Responsible: Chair, Department of OB/GYN
Date of Completion: 2/18/18

Action Plan:
1. Enhancing FBC quality metrics to also include fetal monitoring strip accuracy of interpretation and implemented actions. These will be reported quarterly at the Department of OB/GYN meeting and QAPIC.

Person Responsible: Nurse Manager, FBC
Date of Completion: Reporting to begin in September 2018 and ongoing.

The following is a violation of the State of Connecticut Public Health Code Section 19-13-D3 (b) Administration (2) and/or (e) Nursing Service (1) and/or (i) General (6).

3. *Based on a review of staffing schedules, review of the staffing plan, review of facility documentation and interviews, the facility failed to ensure that the planned staff to patient ratio was maintained in the ICU (intensive care unit). The finding includes:
   a. Review of ICU staffing, staffing plan, patient acuity and patient for the dates of 2/10/18, 2/11/18 and 2/16/18 through 3/2/18. The ICU patient census and/or staffing at the start of the evening shift on 2/10/18 was 20 patients, 5 RNs, 2 NAs and identified that 1 RN cared for 4 ICU level patients for the greater part of the evening shift. Two patients were

newly weaned from ventilators on the day shift, one patient had required a unit of packed red blood cells on the day shift and remained ICU level of care and one patient left AMA (against medical advice) before 7:00PM replaced by a newly admitted patient who required frequent monitoring. Staffing and Census for 2/10/18 into 2/11/18 on the night shift noted a census of 18 patients and NA staffing dropped from 1 to none. The Unsafe Staffing Form dated 2/10/18 and submitted by ICU staff to the Evening Supervisor identified that staff felt that the staffing was not adequate to safely address patient needs with compromises to patient basic hygiene, timely medication administration, and timely patient assessments as required. Review of the email from the evening supervisor dated 2/10/18 indicated that only four nurses were scheduled for the 7:00 PM to 7:00 AM shift, one nurse agreed to stay from 11:00 PM to 3:00 AM and the staffing sheets did not reflect the decrease to 4 nurses for 18 patients after 3:00 AM on 2/11/18. Interview with Nurse Manager #1 on 3/7/18 at 8:12 AM noted that due to nurses leaving, a decrease in ICU nurses and increased patient census in February, the ICU staffing plan could not be met on the evening shift on 2/10/18 and the night shift into 2/11/18. Further interview with the Nurse Manager #1 indicated that the decreased staffing levels were not safe. Interview with the Chief Nursing Officer on 3/8/18 at 2:20 PM indicated that 2/12/17 was the only other reported short staffed day and although calls were made to try to increase staffing on 2/10/18 and 2/11/18, attempts were unsuccessful. The hospital ICU staffing plan identified, in part, that two flex telemetry or intermediate care patients housed in the ICU unit counted as 1 ICU patient and every effort should be made not exceed a three patient assignment.

Action Plan:

1. The ICU staffing plan is designed to allow for flexibility in staffing according to identified needs of the patients. Every attempt is made to maintain staffing ratios of one registered nurse for every two to three patients. In an attempt to maintain these staffing ratios during times of staffing vacancies or surges in census, the following measure(s) are/will be implemented:
    a. Use of per diem floats
    b. Float nurses from other areas and have them care for any "border" patient in ICU or patients that are ready for lower level of care (less acute)
    c. Employee travel/agency nurses
    d. Nurse manager, nurse educator to assist on unit
    e. Use of supportive personnel. This includes health unit secretaries, transport personnel (day shift), use of sitters. Other supportive services include, pharmacists, physical therapists, respiratory therapists, and nursing supervisor.
    f. RN Orientees may be considered as staff assistance- based upon their level of experience and progress in orientation.
    g. Development of a staffing assignment sheet to indicate acuity of patient, so that assignments are created based on not only number of patients, but complexity of patients. Depending on complexity, a nurse may take up to 4

border patients, or those patients identified as being able to transfer to a lower level of care.

Persons Responsible: Sr. VP Patient Care Services/Chief Nursing Officer

Audit: Audit ICU staffing daily as compared to staffing guidelines.

Date of Completion: July 31, 2018

The following are violations of the State of Connecticut Public Health Code Section 19-13-D3 (b) Administration (2) and/or (d) Medical Records (3) and/or (e) Nursing Service (1) and/or (i) General (6).

4. *Based on a clinical record review, staff interviews, and a review of hospital documentation for one of six sampled obstetrical patients (Patient #1), the hospital failed to consistently document the patients output while Magnesium Sulfate was administered and/or failed to consistently document the patient's oxygen saturation and/or failed to conduct oxygen saturations every thirty minutes in the intrapartum period and/or failed to timely remove a balloon catheter utilized for cervical ripening and/or failed to initiate a rapid response when the patient's condition had deteriorated in accordance with the hospital's policies and procedures. The findings included:

a. Review of the clinical record identified Patient #1 was admitted to the hospital on 1/16/18 at 2:43 PM. Patient #1 was thirty eight and one half weeks gestation with severe pre-eclampsia and a known fetal demise. Patient #1 was scheduled for an induction of labor. On arrival to the hospital Patient #1 was afebrile. Initial blood pressures were as follows; 160/100 mmHg and 203/132 mmHg. The clinical record indicated on 1/16/18 Patient #1's blood pressures intermittently continued to be elevated. The patient's blood pressure on 1/16/18 at 6:30 PM was 174/106 mmHg, at 7:33 PM 159/100 mmHg and at 8:50 PM the blood pressure was 167/101 mmHg. Patient #1 intermittently complained of blurred vision, headaches and right upper epigastric pain. The goal was to keep the patients' blood pressure less than 160/100 mm/hg. Hydralazine 10 milligrams (mg) and intravenous (IV) was administered on multiple occasions as a treatment modality for hypertension. Intravenous (IV) Magnesium Sulfate was administered for the prevention of seizures. Pitocin was administered via titration on 1/16/18 and on 1/18/18 for the induction on labor. On both occasions the maximum dose of 20 milliunits/minute was achieved absent progression of labor. Cervidil, Cytotex, and a balloon catheter were utilized for assistance with cervical ripening. Further review of the clinical record identified Patient #1's blood pressures continued to be elevated. On 1/18/18 at 8:31 AM the patient's blood pressure was 167/101 mmHg and at 9:28 AM the blood pressure was 161/103 mmHg. On 1/18/18 at 8:25 PM, Patient #1 became hypotensive with a blood pressure of 81/48 mmHg with a heartrate of 110 beats/minute (normal 60-100 beats/minute), and a temperature of 103 degrees Fahrenheit (normal temperature 98.6 degrees) was noted. Anesthesia was notified and arrived to the patient's room at 8:31 PM with Ephedrine and a fluid bolus being administered. MD #7 was called into the hospital by the nursing staff at 8:33 PM as the patient was managed by a certified midwife who was assisting another patient. MD #7 was at the bedside of Patient #1 at 9:20 PM (40 minutes later). Patient #1 was diagnosed with chorioamnionitis and an emergent Cesarean Section was performed. Patient #2 was delivered stillborn on 1/18/18 at 9:48 PM. Patient #1 remained hypotensive despite the administration of vasopressors. Subsequent to surgery,

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Patient #1 was transferred to the Intensive Care Unit for further management and was ultimately transferred to a higher level of care hospital on 1/19/18 at 3:55 AM for the treatment of sepsis, disseminated intravascular coagulation (DIC) and hemorrhagic shock. Review of the discharge summary from the transferring hospital identified on 1/19/18 at 7:00 AM the patient went into PEA arrest (Pulseless electrical activity) and cardiopulmonary resuscitation was performed. Patient #1 was pronounced deceased on 1/19/18 at 8:25 AM. Review of the autopsy report identified the cause of death as severe preeclampsia leading to intrauterine fetal demise, leading to a cesarean section complicated by septic shock with disseminated intravascular coagulation.

b. Review of the physician's orders identified on 1/16/18 at 6:20 PM Magnesium Sulfate 20 grams/500 ml was ordered for seizure prophylaxis with a loading dose of 4 grams and a maintenance dose of 2 grams/hour. Review of the intake and output shift record identified from 1/16/18 at 6:20 PM through 1/18/18 at 8:30 PM the urine output failed to be documented on three occasions. Interview with Nurse Manager #2 on 3/2/18 at 1:00 PM indicated hourly urine output should have been documented and was not. The hospital policy entitled Management of Pre-eclampsia and Eclampsia directed in part, that when a patient was administered Magnesium Sulfate, the patient's output would be documented hourly.
c. Interview and review of the obstetrical pre-eclampsia assessment sheets with Nurse Manager #2 on 3/2/178 at 1:10 PM identified from 1/16/18 at 6:20 PM through 1/18/18 at 9:12 AM when the patient was in the antepartum period, oxygen saturations failed to be documented on seventeen occasions. Review of the hospital policy entitled Management of Pre-eclampsia and Eclampsia, directed in part, that when a patient was administered Magnesium Sulfate, oxygen saturations would be documented hourly in the antepartum period.
d. Interview with Nurse Manager #2 on 3/2/18 at 1:20 PM indicated the intrapartum period began for Patient #1 on 1/18/18 at 9:12 AM and commencing at that time oxygen saturations should have been conducted every thirty minutes and were not. Review of the obstetrical pre-eclampsia assessment sheets with Nurse Manager #2 identified from 1/18/18 at 9:12 AM through 1/18/18 at 8:30 PM, oxygen saturations failed to be conducted every thirty minutes on eleven occasions. Review of the hospital policy entitled Management of Pre-eclampsia and Eclampsia directed in part oxygen saturations would be documented every thirty minutes in the intrapartum period.
e. Review of the clinical record identified that a balloon catheter was inserted intravaginal on 1/17/18 at 1:23 PM and spontaneously evacuated on 1/18/18 at 9:10 AM, over nineteen hours later. Interview with the Chief of Obstetrics on 3/2/18 at 2:30 PM indicated the balloon catheter should have been removed within twelve hours due to the risk of infection. Interview with Nurse Manager #2 on 3/2/18 at 1:30 PM identified the nurses failed to have a mechanism in place to ensure the balloon catheter would be removed within twelve hours. Review of the hospital policy entitled cervical ripening failed to identify when the balloon catheter should be removed. Subsequent to the investigation, the cervical ripening policy directed the balloon catheter must be removed twelve hours or less after insertion.
f. Interview with Nurse Manager #2 on 3/2/18 at 1:40 PM indicated the nursing staff failed to activate the Rapid Response Team when the patient's condition was deteriorating on 1/18/18

THE FOLLOWING VIOLATION(S) OF THE REGULATIONS OF CONNECTICUT STATE AGENCIES AND/OR CONNECTICUT GENERAL STATUTES WERE IDENTIFIED

at 8:25 PM. The hospital policy entitled Rapid Response Team directed the purpose of a rapid response was to prevent cardiopulmonary arrest in patients showing signs of deterioration through prompt assessment, intervention and stabilization of the patient. The team would be comprised of an intensive care nurse, a hospitalist, and a respiratory therapist. The team would include at least one member that has successfully completed training in Advanced Cardiac Life Support. The rapid response team was to assess the situation and make recommendations for the treatment and stabilization of the patient. The policy further directed that a rapid response may be activated by any staff member for any changes in the patient condition, it the staff member feels the patient's condition is deteriorating.

Further interview with Nurse Manager #2 on 3/2/18 at 1:50 PM indicated after the event on 1/18/18 a debriefing occurred and discussion regarding the activation of a rapid response was communicated however, this discussion was not documented or provided to the entire family birthing staff members.

Interview with the Quality Manager on 3/2/18 at 1:55 PM indicated although a root cause analysis was initiated immediately following the event on 1/18/18, staff interviews had not been conducted, and a comprehensive plan had not been completed.

Subsequent to the surveyor's inquiry an immediate action plan was developed on 3/2/18 that included re-education of the family birthing center (FBC) staff regarding the care delivered in the antepartum, intrapartum, and postpartum phase of the pre-eclamptic patient. The education included a review of policies entitled; Management of Pre-eclampsia and Eclampsia, Management of Acute Hypertensive Crisis in Pregnancy, the Rapid Response Team, and a review of the high reliability organization principle of following the chain of command if needed. In addition the policy for Cervical Ripening was reviewed and revised to ensure documentation of the time when the balloon catheter was inserted, and the time of removal.

Action Plan: An immediate corrective action plan (CAP) was developed and implemented on 3/2/18 which was accepted by the Department of Public Health on 3/2/18. This plan included:

1. The Family Birthing Center (FBC) staff will be immediately re-educated regarding the care delivered in the ante, intra, and post-partum phase of the pre-eclamptic patient. This education included the role and responsibility of the FBC staff while caring for the pre-eclamptic patient.
   a. Review of policy "Management of Pre-eclampsia and eclampsia" with attention to the frequency of vital signs and when to notify the practitioner/AHP.
   b. Review of policy "Management of Acute Hypertensive Crisis in Pregnancy" with attention to frequency of vital signs following medication administration.

Person Responsible: Nurse Manager, FBC

Audit: Audit 5 records per month x3 months to ensure vital signs are appropriately monitored per patient condition.

Date of Completion: Education – 3/16/18; Audits 6/30/18

THE FOLLOWING VIOLATION(S) OF THE REGULATIONS OF CONNECTICUT STATE AGENCIES AND/OR CONNECTICUT GENERAL STATUTES WERE IDENTIFIED

2. FBC staff will be immediately re-educated regarding the roles and responsibilities of the medical and FBC staff.
   a. Review of policy "Management of Pre-eclampsia and eclampsia" with attention to when a physician is required at the bedside.
   b. Review of policy "Management of Pre-eclampsia and eclampsia" with attention to documentation requirement of all communication with provider.

Person Responsible: Nurse Manager, FBC
Audit: Audit 5 records per month x3 months to ensure MD at bedside as appropriate and communication to provider is documented.
Date of Completion: Education – 3/16/18; Audits 6/30/18

3. FBC staff will be immediately re-educated regarding the Rapid Response process and chain of command.
   a. Review of policy "Rapid Response Team" with attention to the criteria for activating the rapid response team in response to a change in patient condition.
   b. Review of High Reliability Organization principle of following the chain of command. In the FBC the staff nurse will make escalating calls to the charge nurse, manager or shift supervisor, medical director of the department, and finally the administrator on call if needed.

Person Responsible: Nurse Manager, FBC
Date of Completion: Education – 3/16/18

4. Review and revise policy "Cervical Ripening" to ensure documentation of the time foley balloon catheter is inserted and the time removed. Time of removal to be investigated to determine evidence-based practice standard in accordance with manufacturer's recommendation. In the interim, it will be kept in no longer than 12 hours.
   Person Responsible: Nurse Manager, FBC

Action Plan: FBC staff will be educated regarding the inclusion of O2 saturation and hourly I&O documentation for the pre-eclamptic/eclamptic patient on Magnesium Sulfate.
Person Responsible: Nurse Manager, FBC
Audit: Review 5 records per month x3 months to ensure documentation of O2 saturation and hourly I&O.
Date of Completion: 7/31/18

Action Plan: Order set to be implement that will prompt nursing staff for removal time of balloon catheter. This has also been added to the shift to shift report template.
Person Responsible: Nurse Manager, FBC
Audit: Review 5 records per month to ensure prompt removal of balloon catheter.
Date of Completion: 7/31/18

The following is a violation of the State of Connecticut Public Health Code Section 19-13-D3 (e)

THE FOLLOWING VIOLATION(S) OF THE REGULATIONS OF CONNECTICUT STATE AGENCIES AND/OR CONNECTICUT GENERAL STATUTES WERE IDENTIFIED

Nursing Service (1).

5. Based on medical record reviews, review of facility policies, observations and interviews for 1 of 3 Patients reviewed for pressure ulcers (Patient #7), the facility failed to ensure that assessment of the ulcer was complete and/or that appropriate treatment was provided. The finding includes:
   a. Patient #7 was admitted to the ICU (intensive care unit with diagnoses that included right shoulder pain. The initial nursing assessment dated 3/4/18 at 5:49 AM identified a stage II pressure ulcer to the coccyx that measured 1cm (L) by 1cm (W) and depth was left blank. The assessment further identified that the wound edges were macerated and an alginate dressing was applied. Review of the wound assessment dated 3/4/18 at 8:00 AM also documented the coccyx ulcer as 1cm by 1cm (depth left blank) and that an alginate dressing was applied. Review of wound consult sheet by Wound Ostomy Nurse #1 (RN) indicated that the Patient's coccyx ulcer measured 2.5cm by 2.5cm (depth not documented) with red wound base, slough to the upper portion of the ulcer, macerated edges and the treatment was changed to Zinc. Physician orders for wound treatment were not present in the patient's medical record. Observation on 3/6/18 at 10:12 am noted Patient #7 lying on an airflow mattress and positioned slightly to the left side. Interview with Wound Ostomy Nurse #2(RN) on 3/6/18 at 2:47 PM noted that a stage II pressure ulcer does have depth and depth should be assessed/documented. Further interview identified that the alginate dressings were used to absorb drainage and Patient #7's documentation did not reflect ulcer drainage and therefore was not an appropriate dressing/treatment. The hospital policy for wound assessment/management identified that partial thickness broken, cracked or blistered skin was considered a stage II pressure ulcer (some depth). The policy further directed to apply alginate dressings to open wounds with large amount of drainage.

Action Plan:

1. The ICU staff were educated, via SBAR, on the correct documentation of moisture, drainage, and the measure of depth for any open wound by 3/19/18.
2. "Wound Assessment and Measurement" education module via HealthStream was assigned to the ICU nurses for completion by 5/30/18
3. Nurses from the ICU will be educated on the need to obtain a physician order for wound treatments when required by our policy, or if using Criteria Based Nursing Action, enter as a protocol order by 4/30/18.
4. Visual aids for dressing selection will be made available on all inpatient units by 4/30/18.
5. The Wound Assessment/Management of Pressure Ulcers and Skin Tears policy, CPM 12.15, was updated to clarify the types of dressings that are appropriate for various types of wounds on 4/30/18.

Person Responsible: Wound Ostomy Nurse

Audit: Review 5 wounds per month x3 months to ensure orders are present when applicable, for wound care, including dressing type, and for presence of documentation of wound measurement, at least weekly, including depth for any open wounds and for correct dressing type according to policy.

THE FOLLOWING VIOLATION(S) OF THE REGULATIONS OF CONNECTICUT STATE AGENCIES AND/OR CONNECTICUT GENERAL STATUTES WERE IDENTIFIED

Date of Completion: 7/31/18

The following are violations of the State of Connecticut Public Health Code Section 19-13-D3 (b) Administration (2).

6. Based on clinical record review, interview and policy review, for two of three patients who filed a grievance (Patient #137 and #102), the hospital failed to respond in accordance with facility policy. The findings include the following:
   a. Patient #137 presented to the Emergency Department (ED) on 10/31/16 at 8:51 AM with complaints of lower back pain that extended to the groin. Review of the clinical record failed to reflect that a pain assessment was completed upon arrival. Review of facility documentation identified that Patient #137 filed a telephone complaint with patient relations on 11/4/16 related to rude staff and failure to address pain. The patient claimed that the triage nurse was very rude, rough and lacked compassion. Interview with the VP of Quality on 5/17/18 at 2:20 PM stated the facility was unable to find any follow-up to the complaint. Interview with the Nurse Manager of the ED on 5/18/18 at 10:15 AM stated she was notified of the complaint and discussed the case with RN #21. Review of the facility policy directed that any statement by a patient or representative that a situation was unsatisfactory or unacceptable is considered a complaint. The policy indicated that once a complaint is filed the complainant should be contacted within 24 hours by the Manager, document the initial complaint in the RL solutions-feedback module and in part provide a follow-up response to the complainant as appropriate.
   b. Patient #102 was evaluated in the ED on 3/21/16 with complaints of vomiting. Review of facility documentation indicated on 8/9/16 a letter was sent to an outside billing agency (not employees of Hospital #1) with complaints about care received by Patient #102 in the ED and charges for services rendered on 3/21/16.
   During an interview with the Chief Compliance and Privacy Officer on 5/21/18 at 12:30 PM he/she indicated the hospital became aware of P#137's concerns on 8/22/16 and was registered as a grievance. According to the Network Chief Compliance and Privacy Officer the subsequent documentation dated 10/31/16 informed P#137 that an investigation related to P#137's concerns about the care he/she received on 3/21/16 had been completed and the results of that investigation (50 days after initial complaint filed as a grievance by the hospital).
   During an interview with the Quality Manager on 5/21/18 at 1:25 PM he/she indicated the hospital could not provide an initial response letter to P#137 in response to the grievance filed by the hospital on 8/22/16.
   The hospital Patient Complaint and Grievance policy indicated all grievances should be acknowledged, if not resolved within 7 business days but no more than 14 business days and have a 30 business day time frame for final follow-up.

Action Plan:

1. Grievance Coordinator during the time of these grievances is no longer employed at Manchester Hospital. The current Grievance Coordinator, Grievance Committee members

and clinical manager/directors will be educated via an email regarding the Complaint/Grievance policy and a powerpoint presentation reminding all of the process and timeframes by 6/25/18.

2. Managers/Directors will be educated at the next systems meeting regarding the Complaint/Grievance policy and a powerpoint presentation reminding all of the process and timeframes on 7/10/18.

Person Responsible: Grievance Coordinator

Audit: Review 5 grievances per month x3 months to ensure compliance with response timeframes.

Date of Completion: 9/30/18

The following is a violation of the State of Connecticut Public Health Code Section 19-13-D3 (b) Administration (2) and/or (c) Medical Staff (2)(B) and/or (i) General (6).

7. *Based on medical record reviews, review of facility policies and interviews for one of three patients who had eye surgery (Patient #127), the facility failed to ensure that the correct lens implant was performed. The finding includes:
   a. Patient #127 was admitted for left phacoemulsification with intraoperative lens implant (IOL) on 3/7/18. The consent form dated 2/15/18, signed by MD #13 and Patient #127, identified left phacoemulsification with IOL. The operative record and/or operative report dated 3/7/18 noted that a "time out" was performed prior to incision and a 17.0 diopter lens was placed in the left eye. Review of MD #13's office note dated 3/8/18 indicated that, although the hospital was notified of a lens change for the Patient, the myopic lens was still inserted (in error) and Patient #127 agreed to go forward with a lens exchange. The operative report dated 3/8/18 identified that the Patient had an IOL exchange and had a 14.0 diopter lens implanted following removal of the previous lens. Interview with RN #11 on 5/17/18 at 10:13 AM noted that she pulled the lenses for all MD #13's eye cases on 3/2/18 and the lens order sheet with the change in Patient #127's lens was not present at that time. Interview with the OR Scheduler on 5/7/18 at 10:40 AM and review of the revised lens order sheet indicated that she received the changed lens order sheet on 3/2/18 at 2:24 PM and placed it backwards on the hall cork board per usual. Interview with the RN #12 (Circulator Nurse for 3/7/18) on 5/18/18 at 10:11 AM indicated that once lenses were pulled, the board was not checked for updates and the correct lens was inserted per the first lens order sheet. MD #13 was unavailable for interview at the time of the investigation. The facility Universal Protocol policy identified, in part, that a "Time Out" will be performed by the surgical team.

Action Plan:

1. A new lens order sheet was created to clearly define the dating and timing of the order
   a. The surgeon's office staff was educated to this revised form by 3/16/18.
   b. OR clerical staff has been educated regarding the process for lens order receipt by 3/9/18.
   c. The OR staff was re-educated regarding the verification process when preparing a lens order and the intraoperative process by 5/31/18.

d. The eye surgeons were educated to bring in a lens list from their office and to compare the lens chosen with his/her list order during the time out by 5/18/18

Person Responsible: Clinical Coordinator, OR

Audit: Review 5 cases per month x3 months to ensure compliance with verification of lens order process and intra-operative verification process

Date of Completion: 8/31/18

The following is a violation of the State of Connecticut Public Health Code Section 19-13-D3 (b) Administration (2) and/or (c) Medical Staff (2)(B) and/or (i) General (6).

8. *Based on a review of the clinical record, staff interviews and a review of facility documentation for one of one sampled patient (Patient #133), reviewed for the retention of surgical packing following an operative procedure, the facility failed to remove vaginal packing prior to discharge. The finding included:
   a. Review of the clinical record identified Patient #133 was admitted to the hospital on 2/9/18 who underwent a bilateral salpingo-oopherectomy and a TVT (tension-free vaginal tape) due to pelvic pain and a right ovarian nodule. Vaginal packing was inserted at the end of the procedure due to bleeding. Patient #133 was discharged to home on 2/10/18. Further review of the clinical record indicated Patient #133 called from home to inform the discharging unit that she removed the vaginal packing at home.
   Interview with RN #41 on 5/17/18 at 10:15 AM, who was the circulating nurse in the operating room, identified vaginal packing was not part of the operative count. RN #41 indicated she does not recall if vaginal packing was inserted or if that information was communicated to her.
   Interview with MD #41 on 5/17/18 at 11:55 AM, who was the surgeon, indicated she should have written an order to remove the vaginal packing immediately following the operative procedure and did not.
   Interview with Quality Manager #2 identified it was the responsibility of the surgeon to write an order to remove the packing prior to discharge. Subsequent to the event an operating room report checklist was developed that in part included the presence or absence of packing.

Action Plan:

1. The surgeons involved in the case were coached one on one on 2/12/18.
2. The Department of OB/GYN has been reminded that an order is required for a nurse to remove packing. A blast e-mail was sent to the OB/GYN department by the Chair. On 2/23 and this was also discussed at the Dept. of OB/GYN meeting on 2/23/18 and the Dept. of Surgery meeting on 3/19/18.

Person Responsible: Chair, Department OB/GYN, Chair, Department of Surgery

3. The OR staff involved in the case was coached one on one regarding handoff communication on 2/12/18.
4. A handoff checklist has been created and implemented. This checklist is to be used at the time of handoff/transfer to the receiving unit. Staff was educated regarding the checklist by 2/14/18.

THE FOLLOWING VIOLATION(S) OF THE REGULATIONS OF CONNECTICUT STATE AGENCIES AND/OR CONNECTICUT GENERAL STATUTES WERE IDENTIFIED

Person Responsible: Director, Perioperative Services
Audit: Handoff communication will be randomly reviewed in 5 cases per month x3 months.
Date of Completion: 5/31/18

The following is a violation of the State of Connecticut Public Health Code Section 19-13-D3 (c) Medical Staff (2)(B) and/or (e) Nursing Service and/or (i) General (6).

9. Based on interview and a review of the hospital's policy and procedure for the administration of Nitrous Oxide, the policy failed to indicate a dose, frequency or duration for the administration of Nitrous Oxide. The finding included:
   a. Review of the Nitrous Oxide Policy and interview with Nurse Manager #2 on 5/14/18 at 10:20 AM identified Nitrous Oxide would be inhaled as a 50-50 blend of Oxygen and Nitrous Oxide however, the policy failed to identify a dose, frequency or duration of administration and should have.

Action Plan: Nitrous Oxide Policy and order set to be revised to include nitrous oxide in a 50/50 blend, as needed, during labor or for postpartum procedures.
Person Responsible: Nurse Manager, FBC
Date of Completion: 6/30/18

The following is a violation of the State of Connecticut Public Health Code Section 19-13-D3 (b) Administration (2) and/or (c) Medical Staff (2)(B) and/or (e) Nursing Service (1) and/or (i) General (6).

10. *Based on a review of clinical records, staff interviews and a review of hospital documentation for one of two mother/infant dyads reviewed in the intrapartum stage of labor (Patient # 134 and #134A), the hospital failed to accurately assess a non-reassuring fetal tracing and subsequently implement interventions timely to promote the highest level of well-being. The finding included:
    a. Review of the clinical record identified Patient #134 was admitted to the hospital on 8/11/16 at 11:25 PM who presented in labor at thirty eight weeks gestation. Interview and review of the fetal tracing with the Chief of Obstetrics on 5/22/18 at 4:30 PM from 11:25 PM through 11:58 PM identified moderate variability (variability is defined as fluctuations in the fetal heart rate and is an indicator of a normal functioning central nervous system). On 8/12/16 at 12:15 AM minimal variability (persistent minimal or absent fetal heart rate (FHR) variability is a sign of fetal compromise), was present absent accelerations of the fetal heart rate, (a fetal heart acceleration is an increase in the FHR greater or equal to ten beats per minute above the baseline with a duration of ten seconds or more from the most recently calculated baseline accelerations and is considered a sign of fetal well-being) until 12:59 AM. Ten liters of oxygen via a non-rebreather was administered to Patient #134 at this time. Further interview and review of the clinical record with the Chief of Obstetrics indicated at 1:09 AM and 1:10 AM possible late decelerations (late decelerations indicates an increased risk of fetal acidosis secondary to utero-placental insufficiency) occurred. From 1:10 AM through 2:01 AM minimal variability continued without FHR accelerations. At 1:55 AM a position change

to high fowlers was made. A popsicle and juice was provided at 1:20 AM and 1:30 AM respectively. Late decelerations recurred at 2:02 AM and 2:05 AM. From 2:06 AM through 2:28 AM the tracing continued with minimal variability and lacked accelerations. At 2:29 AM MD #43 and (Nurse Midwife) NM #5 had reviewed the fetal tracing at the nurse's station. At 2:32 AM a late deceleration was identified. At 2:43 AM a bolus of intravenous fluid was administered. Minimal variability and absent accelerations continued from 2:33 AM through 3:48 AM despite resuscitative interventions. An epidural was administered at 3:24 AM. Late decelerations were noted at 3:49 AM, 3:53 AM and 4:00 AM. The fetal tracing from 4:01 AM through 5:02 AM continued with absent accelerations and minimal variability. At 5:03 AM the baseline FHR decreased from 140 beats per minute to 120 beats per minute. At 5:12 AM, a prolonged deceleration to 60 beats per minute was identified. At 5:20 AM, MD #43 performed a vaginal exam, ruptured membranes and applied an internal fetal electrode that verified the FHR of 60 beats/minute. Thick dark meconium fluid was noted. Patient #134 was taken to the operating room at 5:24 AM for a stat Caesarean Section. Patient #134A was delivered at 5:36 AM with apgar scores of 0, 0, and 4. Positive pressure ventilation was immediately administered and Patient #134A was intubated at 2 minutes of life. Chest compressions were initiated and Epinephrine was administered via the endotracheal tube with a heartrate above 60 beats/minute at 8 minutes of life. Patient #134A was transferred to the neonatal intensive care unit with an initial PH of 6.89. (Normal value 7.35-7.45). The neurological examination revealed abnormal reflexes, minimally reactive pupils, central hypotonia with extremity hypertonia and generalized clonus. The clinical impression was that of severe neonatal encephalopathy and a concern for long term neurologic impairment was prognosticated. Patient #134A was transferred to an alternate acute care facility for therapeutic hypothermia.

Review of the transferring hospital documentation identified hypothermia was induced for 72 hours with subsequent warming. Patient #134A required vasopressors for support and was extubated on 8/16/16. A percutaneous gastrostomy tube was surgically placed on 9/6/16 for continuous feedings. Hypoxic-ischemic encephalopathy stage three was diagnosed with probable electrographic seizures and a poor clinical outcome. Multiple consultations were obtained throughout hospitalization and several outpatient providers were recommended at the time of discharge and included a home health agency, surgery, neurology, ophthalmology, pediatric services and birth to three.

Further interview and review of the fetal tracing with the Chief of Obstetrics on 5/22/18 at 4:30 PM identified the first half hour of the fetal tracing was not concerning as moderate variability with fetal accelerations were identified however, after the first half hour, minimal variability, absent accelerations and a contraction pattern that was intermittently indeterminate ensued. At 1:09 AM, 1:10 AM, 2:02 AM and 2:05 AM late decelerations were present despite several resuscitative interventions. The Chief of Obstetrics indicated the standard of care would have been to perform a Cesarean Section at approximately 2:00 AM, after two hours of resuscitative interventions did not improve the fetal tracing.

Subsequent to the surveyors inquiry an immediate plan of correction dated 5/23/18 directed in part that the medical staff would be educated in the management of fetal

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monitoring. Mandatory education would be provided as part of continuing education. In addition, immediate education would be provided by one to one mentoring in the management of electronic fetal monitoring to the providers that were involved in the case, by the Department Chair or designee until formal education was provided.

Action Plan:

1. All OB medical staff were educated in the interpretation of electronic fetal monitoring strips (EFM). This education has been implemented in the form of GNOSIS training (an electronic educational program.) The training included the recognition of abnormal fetal tracings. All medical staff has completed this training. Training took place May 3, 2017 – February 21, 2018.
2. Immediate education of OB medical staff will be provided via 1:1 mentoring in the management of EFM by the Department Chair or designee until formal education is provided by 6/18/18.
3. FBC staff will be educated in the management of EFM. This mandatory education will be provided as part of continuing education. The initial planning of this educational program was implemented 5/22/18.

Person Responsible: Chair, Department of OB/GYN
Audit: A sampling of EFM strips will be reviewed for accuracy of interpretation and implementation of actions for a 3 month period of time.
Date of Completion: 7831/18

Action Plan:

1. All FBC medical and nursing staff were educated in the interpretation of electronic fetal monitoring strips (EFM).
    a. This education has been implemented in the form of GNOSIS training (an electronic educational program). This training included the recognition of abnormal fetal tracings. All FBC medical staff and nursing staff has completed this training. Training took place between 5/3/17 and 2/21/18. Nurses who scored low on knowledge or judgement (or both) were required to complete additional remediation modules. The FBC nurse educator audits nursing staffs' EFM once each month and provides feedback on an individual basis.
    b. All FBC nursing staff will obtain certification in the interpretation of fetal monitoring over the next 18 months. Began process of certification 5/21/18.
    c. The nurse involved (interviewed) will be mentored one on one by the FBC nurse educator in the assessment and recognition of late decelerations. Planning for the implementation of this mentoring was initiated 5/23/18 and completed 5/31/18.

Person Responsible: Nurse Manager, FBC
Audit: review 5 records per month x3 months to ensure accuracy of EFM interpretation.
Date of Completion: 8/31/18

The following are violations of the State of Connecticut Public Health Code Section 19-13-D3 (e) Nursing Service (1).

THE FOLLOWING VIOLATION(S) OF THE REGULATIONS OF CONNECTICUT STATE AGENCIES AND/OR CONNECTICUT GENERAL STATUTES WERE IDENTIFIED

11. Based on a review of clinical records, interview and policy review, for two of three patients reviewed for pain (Patient #136 and #137), the hospital failed to ensure the patient's pain was assessed and/or reassessed following the administration of medication in accordance with facility policy. The findings include the following:
    a. Patient #136 presented to the Emergency Department (ED) on 3/18/17 at 8:14 PM with complaints of weakness and being dizzy for several weeks. Review of the physician note dated 3/18/17 at 10:48 PM indicated that the patient's symptoms were moderate to severe and worse when standing. The record reflected that intravenous fluids were administered and that an "ambulatory trial" was completed however the patient felt that he/she was not able to go home. A nurse's note dated 3/19/17 at 12:00 AM identified that the patient complained of back pain and that Tylenol 1000 milligrams (mg) was administered at 1:20 AM. The record failed to reflect an assessment of the patient's level of pain and/or a reassessment of the patient's level of pain to determine if the Tylenol was effective.
    Review of the facility policy indicated that the patients will have their level of pain reassessed after medication administration or an intervention provided to relieve pain.
    b. Patient #137 presented to the ED on 10/31/16 at 8:51 AM with complaints of lower back pain that extended to the groin. Review of the clinical record with the Nurse Manger on 5/18/18 at 10:15 AM failed to reflect that a pain assessment was completed on arrival. The record indicated that Dilaudid 1 mg and Toradol 30 mg intravenously were administered at approximately 9:30 AM although there was no pain assessment documented.

Action Plan: The ED nursing staff were educated, via a powerpoint presentation in HealthStream on the need to assess all patients for pain and level of pain, starting at Triage, after any pain intervention and prior to discharge. Reassessment of pain level, after treatment, is also required.
Person Responsible: Nurse Manager, ED
Audit: Review 5 records per month x3 months to ensure all patients have a pain assessment documented, including level of pain at triage, with treatment, and prior to discharge, and have a documented reassessment of pain level after treatment.
Completion date: 8/31/18

The following is a violation of the State of Connecticut Public Health Code Section 19-13-D3 (e) Nursing Service (1) and/or (i) General (6).

12. *Based on a review of the clinical record, staff interviews and a review of facility documentation for one of three sampled patients reviewed for infant falls (Patient #132), the facility failed to observe the mother infant dyad hourly in accordance with the hospital policy. The finding included:
    a. Review of the clinical record identified Patient #131 was admitted to the hospital on 6/16/17 at forty one weeks gestation for an induction of labor. Patient #132 was delivered via a spontaneous vaginal delivery on 6/16/17 at 2:11 PM. On 6/17/17, at 11:45 PM Patient #131 received Tylenol for pain and a comprehensive reassessment

was completed on 6/18/17 at 12:45 AM. On 6/18/17 at 3:45 AM, Patient #131 called for a nurse and indicated she was awakened by her infant crying. The infant was found on the floor of the patient's room. The patient's bed was noted to be in the high position (3.5 feet), when the nursing staff entered the room. Patient #131 indicated she last fed the baby at 2:00 AM. Patient #131 was transferred to the nursery for an examination and observation. An immediate assessment did not identify trauma or neurological abnormalities. On 6/18/17 at 5:00 AM, Patient #131 experienced central apneic episodes with oxygen desaturation that required vigorous stimulation to recover. At 7:30 AM, Patient #131 was transferred to an alternate hospital for a higher level of care.
Interview and review of the clinical record on 5/17/18 at 10:30 AM with RN #42, who was the patient's nurse, identified the last time a staff member was in the room was on 6/18/17 at 12:45 AM, three hours before the infant fell. Although the patient indicated she feed the infant at 2:00 AM that was a verbal report provided by the patient and not a direct observation.
Interview with RN #43 on 5/17/18 at 11:55 AM, who was a staff nurse on duty indicated she does not recall the time or if the infant was in the arms of the patient but does recall she informed Patient #131 that the hospital bed needed to be in the lowest position. RN #43 lowered the patient's bed at some point during the night shift.
Interview and review of the clinical record with Nurse Manager #2 on 5/17/18 at 2:30 PM failed to identify that the staff had conducted hourly rounds. Nurse Manager #2 indicated it was the expectation to visually observe the mother and infant dyad hourly.
Review of the transferring hospital discharge summary identified Patient #132's imaging revealed a small subarachnoid hemorrhage overlying the left frontal-parietal area. Neurosurgery was consulted and not further workup was recommended. Patient #132 was discharged to home on 6/25/17.
The hospital policy entitled Newborn Fall Prevention and Management directed in part that at any time that adult caretaker(s) plan to sleep or feel that they are close to falling asleep, the infant must be in a crib for safety. The policy further directed that staff members would open doors to patient rooms at least hourly, identify self, and ensure that if the infant is in arms, the adult holding him/her is not asleep or does not appear sleepy. If both mother and infant are asleep in their respective beds, they would be visualized and not disturbed.

Action Plan:

1. The current policy will be revised to reflect rounding with a purpose. The rounding will be documented in meditech with rounding topics specific to the FBC mom and infant. Safe sleep will be reviewed each shift with mom and family and documented in the EMR.
2. FBC post-fall assessment will be added to Meditech to assist in the tracking and trending and evaluation of any infant falls.
3. The unit to discuss the implementation of a FBC unit based falls committee.
4. Staff will be educated regarding rounding topics and safe sleep being part of the shift assessment for all moms and family.

Person Responsible: Nurse Manager, FBC

Audit: Review 5 records per month x3 months to ensure documentation of purposeful

rounding and safe sleep assessments every shift.
Completion date: 6/30/18

The following is a violation of the State of Connecticut Public Health Code Section 19-13-D3 (c) Medical Staff (2)(B) and/or (e) Nursing Service (1) and/or (i) General (6).

13. *Based on a review of clinical records, staff interviews and a review of hospital documentation for one of two mother/infant dyads reviewed in the intrapartum stage of labor (Patient # 134 and #134A), the hospital failed to accurately assess a non-reassuring fetal tracing and subsequently implement interventions timely to promote the highest level of well-being. The finding included:
    a. Review of the clinical record identified Patient #134 was admitted to the hospital on 8/11/16 at 11:25 PM who presented in labor at thirty eight weeks gestation. Interview and review of the fetal tracing with the Chief of Obstetrics on 5/22/18 at 4:30 PM from 11:25 PM through 11:58 PM identified moderate variability (variability is defined as fluctuations in the fetal heart rate and is an indicator of a normal functioning central nervous system). On 8/12/16 at 12:15 AM minimal variability (persistent minimal or absent fetal heart rate (FHR) variability is a sign of fetal compromise), was present absent accelerations of the fetal heart rate, (a fetal heart acceleration is an increase in the FHR greater or equal to ten beats per minute above the baseline with a duration of ten seconds or more from the most recently calculated baseline accelerations and is considered a sign of fetal well-being) until 12:59 AM. Ten liters of oxygen via a non-rebreather was administered to Patient #134 at this time. Further interview and review of the clinical record with the Chief of Obstetrics indicated at 1:09 AM and 1:10 AM possible late decelerations (late decelerations indicates an increased risk of fetal acidosis secondary to utero-placental insufficiency) occurred. From 1:10 AM through 2:01 AM minimal variability continued without FHR accelerations. At 1:55 AM, a position change to high fowlers was made. A popsicle and juice was provided at 1:20 AM and 1:30 AM respectively. Late decelerations recurred at 2:02 AM and 2:05 AM. From 2:06 AM through 2:28 AM the tracing continued with minimal variability and lacked accelerations. At 2:29 AM, MD #43 and (Nurse Manager) NM #5 had reviewed the fetal tracing at the nurse's station. At 2:32 AM, a late deceleration was identified. At 2:43 AM, a bolus of intravenous fluid was administered. Minimal variability and absent accelerations continued from 2:33 AM through 3:48 AM despite resuscitative interventions. An epidural was administered at 3:24 AM. Late decelerations were noted at 3:49 AM, 3:53 AM and 4:00 AM. The fetal tracing from 4:01 AM through 5:02 AM continued with absent accelerations and minimal variability. At 5:03 AM, the baseline FHR decreased from 140 beats per minute to 120 beats per minute. At 5:12 AM, a prolonged deceleration to 60 beats per minute was identified. At 5:20 AM, MD #43 performed a vaginal exam, ruptured membranes and applied an internal fetal electrode that verified the FHR of 60 beats/minute. Thick dark meconium fluid was noted. Patient #134 was taken to the operating room at 5:24 AM for a stat Caesarean Section. Patient #134A was delivered at 5:36 AM with apgar scores of 0, 0, and 4. Positive pressure ventilation was immediately administered and Patient #134A was intubated at 2 minutes

of life. Chest compressions were initiated and Epinephrine was administered via the endotracheal tube with a heartrate above 60 beats/minute at 8 minutes of life. Patient #134A was transferred to the neonatal intensive care unit with an initial PH of 6.89. (Normal value 7.35-7.45). The neurological examination revealed abnormal reflexes, minimally reactive pupils, central hypotonia with extremity hypertonia and generalized clonus. The clinical impression was that of severe neonatal encephalopathy and a concern for long term neurologic impairment was prognosticated. Patient #134A was transferred to an alternate acute care facility for therapeutic hypothermia.

Review of the transferring hospital documentation identified hypothermia was induced for 72 hours with subsequent warming. Patient #134A required vasopressors for support and was extubated on 8/16/16. A percutaneous gastrostomy tube was surgically placed on 9/6/16 for continuous feedings. Hypoxic-ischemic encephalopathy stage three was diagnosed with probable electrographic seizures and a poor clinical outcome. Multiple consultations were obtained throughout hospitalization and several outpatient providers were recommended at the time of discharge and included a home health agency, surgery, neurology, ophthalmology, pediatric services and birth to three.

Further interview and review of the fetal tracing with the Chief of Obstetrics on 5/22/18 at 4:30 PM identified the first half hour of the fetal tracing was not concerning as moderate variability with fetal accelerations were identified however, after the first half hour, minimal variability, absent accelerations and a contraction pattern that was intermittently indeterminate ensued. At 1:09 AM, 1:10 AM, 2:02 AM and 2:05 AM late decelerations were present despite several resuscitative interventions. The Chief of Obstetrics indicated the standard of care would have been to perform a Cesarean Section at approximately 2:00 AM, after two hours of resuscitative interventions did not improve the fetal tracing.

Interview with RN #45 on 5/22/18 at 11:30 AM indicated that she documented moderate variability and the presence of accelerations intermittently in the clinical record when today she would have identified the variability as minimal and lacking accelerations. RN #45 also indicated she did not recognize the late decelerations in the fetal tracing. RN #45 identified at the time of this case she had been a labor and delivery nurse for less than a year and that the lack of experience was likely why she did not interpret the tracing correctly. RN #45 indicated the providers were present during labor and she relied on the practitioners who were present to intervene if needed.

Interview with Nurse Manager #2 on 6/6/18 at 10:50 AM identified RN #45 should have been able to identify the abnormal fetal tracing. Subsequent to the surveyors investigation RN #45 was provided individual training on abnormal fetal tracings.

Further interview with Nurse Manager #2 indicated although the hospital policy entitled Fetal Monitoring and Interpretation defined terminology for the assessment of fetal tracings it failed to direct interventions and a reporting mechanism when fetal tracings were abnormal or concerning.

Subsequent to the surveyors inquiry an immediate plan of correction dated 5/23/18 directed in part that the nurse involved in the case would be mentored by the nurse educator in the assessment and recognition of abnormal fetal tracings. In addition, all nursing staff would be obtaining certification in the interpretation of fetal monitoring

THE FOLLOWING VIOLATION(S) OF THE REGULATIONS OF CONNECTICUT STATE AGENCIES AND/OR CONNECTICUT GENERAL STATUTES WERE IDENTIFIED

over the next eighteen months

Action Plan:

1. The FBC medical staff will be educated in the interpretation of electronic fetal monitoring strips (EFM). This education has been implemented in the form of GNOSIS training (an electronic educational program). This training included the recognition of abnormal fetal tracings. All FBC medical staff has completed this training. Training took place May 3, 2017-February 21, 2018.
2. Immediate education will be provided via 1:1 mentoring in the management of EFM by the Department Chair or designee until formal education is provided by 6/18/18.
3. The FBC medical staff will be educated in the management of EFM. This education will be provided as part of continuing education. The initial planning of this educational program was implemented 5/22/18.

Person Responsible: Chair, Department OB/GYN
Audit: Moving forward a sampling of EFM strips will be reviewed for accuracy of interpretation and implementation of actions for a 3 month period.
Completion date: 8/31/18

4. All FBC nursing staff were educated in the interpretation of electronic fetal monitoring strips (EFM). This education has been implemented in the form of GNOSIS training (an electronic educational program). The training included the recognition of abnormal fetal tracings. All FBC nursing staff has completed this training between 5/3/17 through 2/21/18. Nurses who scored low on knowledge or judgement (or both) were required to complete additional remediation modules. The FBC nurse educator audits nursing staffs' EFM once each month and provides feedback on an individual basis.
5. All FBC nursing staff will obtain certification in the interpretation of fetal monitoring over the next 18 months. Began process of certification 5/21/18.
6. The nurse involved (interviewed) will be mentored 1:1 by the FBC educator in the assessment and recognition of late Decelerations. Planning for the implementation of this mentoring was initiated 5/23/18 and completed 5/31/18.
7. The current policy, Fetal Monitoring and Interpretation, will be updated to include direct interventions and a reporting mechanism when fetal tracings become abnormal or concerning. Staff will be educated regarding the policy changes.

Person Responsible: Nurse Manager, FBC
Audit: Review 5 records per month for 3 months for accuracy of EFM interpretation.
Completion date: 8/31/18

The following are violations of the State of Connecticut Public Health Code Section 19-13-D3 (d) Medical Records (3) and/or (e) Nursing Service (1).

14. Based on a review of clinical records, interview and policy review, for two of three patients reviewed in the outpatient behavioral health clinic (#147 and #149), the hospital failed to ensure that the treatment plans were updated in accordance with facility policy. The

THE FOLLOWING VIOLATION(S) OF THE REGULATIONS OF CONNECTICUT STATE AGENCIES AND/OR CONNECTICUT GENERAL STATUTES WERE IDENTIFIED

findings include the following:

a. Patient #147 presented to the facility on 4/26/18. The clinical record indicated that the patient was evaluated, a treatment plan was completed and the patient was placed in the partial hospital program. The 5/14/18 physician re-evaluation recommended that the patient be admitted to the intensive outpatient program (IOP). The patient started in the IOP on 5/15/18 and a weekly case review was completed on 5/18/18. Review of the record with the Program Director on 5/24/18 failed to reflect that the treatment plan was updated when the patient's level of care had been changed.
b. Review of Patient #149's clinical record indicated that in April of 2017 the patient had been in the IOP and was transitioned to outpatient care. The clinical record indicated that on 5/15/18 the patient requested IOP secondary to the reemergence of suicidal ideation. The patient restarted IOP on 5/15/18 however review of the record with the Program Director on 5/24/18 failed to reflect that a treatment plan was completed. Review of the treatment plan policy indicated that treatment plans are to be updated every thirty days for PHP/IOP patients or as the level of care changes.

Action Plan: Treatment planning policy has been revised to indicate timelines for updating treatment plans. Staff has been educated regarding timeline for updating treatment plans.
Person Responsible: Director, Outpatient Behavioral Health
Audit: Review 5 records per month for 3 months to ensure treatment plans are updated in accordance with the timeframe in the policy.
Completion date: 8/31/18

The following is a violation of the State of Connecticut Public Health Code Section 19-13-D3 (e) Nursing Service (1) and/or (i) General (6).

15. Based on medical record review, review of facility policies and interviews for one of three patients who was administered a medication that required titration (Patient #143), the facility failed to ensure that patient assessments were completed as per facility policy. The finding includes:
    a. Patient #143 was admitted to the ICU (intensive care unit) on 5/14/18 with possible overdose and required mechanical ventilation. Review of physician orders dated 5/15/18 at 6:00 PM directed Propofol 1000mg/100ml with an initial rate of 5mcg/kg/min. The order further directed to titrate by 5mcg/kg every 5 minutes to achieve a SAS (sedation/agitation scale) of 0 to -1. Review of the Propofol infusion rates and hourly SAS on 5/17/18 at 12:54 PM identified that the documentation was lacking on 5/16/18 at 12:00 AM, 1:00 AM, 7:00 AM, 3:00 PM and 11:00 PM. In addition, documentation of the hourly Propofol drip rate and SAS were not documented for the entire night shift on 5/17/18 from 12:00 AM to 7:00 AM. Interview with the ICU Manager on 5/17/18 at 1:27 PM indicated that hourly documentation of the Propofol infusion and SAS was required in the ICU. The ICU Manager further identified that the RNs would document the missing data and, per policy, nurses had 24 hours to add an addendum to the record. Although the documenting corrections and addenda policy identified that addenda are documented in the legally accepted method no greater than

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24 hours, the Propofol policy identified that documentation included the rate and a SAS every hour.

Action Plan:

1. ICU nursing staff were re-educated on the Critical Care Policy CCPPM 2.86 – Use of the Sedation-Agitation Scale, which states "The patient's response to therapy is documented in the Nursing Interventions sedation record documentation screen in EMR every hour and prn".
2. ICU nursing staff were re-educated on the Critical Care policy CCPPM 3.50 – Diprivan (Propofol) Protocol for continuous Sedation in the ICU and ED.
3. New screens were created to include the Sedation/Agitation scale with titration documentation for sedative medications. The prior Sedation/Agitation documentation intervention has been removed.

Person Responsible: Nurse Manager, Critical Care Suites
Audit: Review 5 records per month for 3 months to ensure hourly documentation of sedation/agitation scores and drip rates.
Completion date: 8/31/18

The following is a violation of the State of Connecticut Public Health Code Section 19-13-D3 (c) Medical Staff (2)(B).

16. Based on a review of the clinical record, staff interviews and a review of the hospital policy for one sampled patient reviewed for the administration of Nitrous Oxide (Patient #117), the facility failed to ensure a telephone order was sign timely in accordance with the hospital policy. The finding included:
    a. Review of the clinical record identified Patient #117 was admitted to the hospital on 5/2/18 in labor. Physician's orders directed the use of Nitrous Oxide for analgesia. Interview and review of the clinical record with Nurse Manager #2 on 5/14/18 at 10:00 AM indicated the order was received by a nurse via a telephone order on 5/2/18 at 11:36 PM. The physician failed to sign the order until 5/7/18 at 10:44 AM. Further interview with Nurse Manager #2 indicated the order should have been signed on the same day in was entered and was not. The hospital policy entitled Medical Orders directed in part that a registered nurse can accept and document telephone or verbal orders from a practitioner. All telephone or verbal orders should be entered in the patient's medical record immediately, reviewed, and countersigned by the prescriber as soon as possible.

Action Plan: Department of OB/GYN providers were re-educated at the 5/21/18 and 6/18/18 Department of OB/GYN meetings. A memo was sent to OB/GYN providers by the Chair, Dept. OB/GYN on 5/31/18 regarding verbal order requirements with a return signature read receipt request.
Person Responsible: Chair, Dept. OB/GYN
Audit: Review 5 records per month for 3 months to ensure verbal orders are signed off in a timely manner.
Completion date: 8/31/18

THE FOLLOWING VIOLATION(S) OF THE REGULATIONS OF CONNECTICUT STATE AGENCIES AND/OR CONNECTICUT GENERAL STATUTES WERE IDENTIFIED

The following is a violation of the State of Connecticut Public Health Code Section 19-13-D3 (d) Medical Records (3) and/or (e) Nursing Service (1).

17. Based on medical record reviews, review of facility policies and interviews for one of three patients who had a blood transfusion (Patient #114), the facility failed to ensure that transfusion documentation was accurately recorded. The finding includes:
    a. Patient #114 was admitted to the ambulatory infusion area for a blood transfusion on 5/15/18. Observations on 5/15/18 at 11:23 AM noted Patient #114 in the chair with one unit of blood infusing. The transfusion record dated 5/18/18 identified that the blood was initiated at 11:10 AM. The record also noted that although the signature of the Transfusionist was present, the second signature of the verifying individual was left blank. Interview with RN #14 on 5/15/18 at 11:26 AM noted that she verified the blood for patient #114 prior to infusion initiation and forgot to sign the transfusion record. The facility policy for transfusion therapy identified that both verifying staff must sign their names on the infusion therapy paper.

Action Plan: Nurses in the AMU were re-assigned the Blood Transfusion Review power point presentation which includes instructions that both staff members must sign the unit transfusion card.
Person Responsible: Nurse Manager, AMU
Audit: Review 5 blood transfusion per month for 3 months to ensure documentation of the second verification signature.
Completion date: 8/31/18

The following is a violation of the State of Connecticut Public Health Code Section 19-13-D3 (b) Administration (2).

18. Based on observation of the Radiology Department, staff interviews and a review of the facility documentation, the hospital failed to ensure an acceptable level of safety and quality. The finding included:
    a. On 5/14/18 at 2:00 PM a tour of the Magnetic Resonance Imaging (MRI) area identified multiple needles were stored in a cabinet that was left unlocked. This area was not in direct observation of a staff member. Interview with the Clinical Quality Educator of Radiology on 5/14/18 at 2:05 PM indicated the cabinet should have been secured and was not. Subsequent to surveyor inquiry, the Clinical Quality Educator of Radiology locked the cabinet.

Action Plan: Sharps have been moved to a secure location with contrast that requires being locked at all times. Medical Imaging staff has been educated to secure all sharps.
Person Responsible: Assistant Director, Medical Imaging
Audit: Audit securement of sharps in MRI area 5 times per month for 3 months to ensure compliance.
Completion date: 8/31/18

THE FOLLOWING VIOLATION(S) OF THE REGULATIONS OF CONNECTICUT STATE AGENCIES AND/OR CONNECTICUT GENERAL STATUTES WERE IDENTIFIED

The following are violations of the State of Connecticut Public Health Code Section 19-13-D3 (f) Diagnostic and therapeutic facilities and/or (i) General (6).

19. Based on clinical inspection of radiological services, the hospital failed to ensure that safety precautions were maintained. The findings include:
    a. In accordance with Section 19-24-7 Surveys:
    (A) (1.) As used in section 19-24-1-19-24-14 inclusive "survey" means an evaluation of the radiation hazards incident to the receipt, transfer, possession, manufacture, storage, use, operation, handling, transportation or disposal of radioactive materials or other sources of radiation under a specific set of conditions. Where appropriate, such evaluation shall include a physical survey of the location of materials and equipment and measurements of levels of radiation or concentrations of radioactive material present.
    (2.) Each owner of an installation shall make or cause to be made such surveys as may be necessary to comply with sections 19-24-1 through 19-24-14 inclusive.
    (3.) The adequacy of surveys shall be subject to the review of the department's representatives.
    (B.) Each owner shall maintain records showing the results of the surveys.
    Contrary to these requirements, surveys in the lung perfusion study room failed to adequately evaluate radiological hazards associated with Xe-133. Specifically:
    " The Victoreen instrument utilized to measure Xe-133 gas radioactivity was not maintained within manufacturer's guidance for calibration. Manufacturer guidance requires annual calibration. Calibration records showed that the instrument was last calibrated over one year ago (by Manchester Hospital maintenance staff).
    " Failure to maintain gas intake flow port filter resulted in excessive filter loading that prevented proper survey of radiation concentrations. DEEP personnel identified to Manchester Hospital Staff that the manufacturer label near the flow intake port states "clean filter weekly". Filter loading level buildup indicating that this maintenance was not performed weekly. Measurements of Xe-133 are not representative of maximum concentrations. Xe-133 gas is heavier than air. The instrument is placed at a breathing zone level to conduct surveys. The instrument should be placed in a location more indicative of a true measurement of the maximum airborne concentrations in the room (near floor).
    Observations:
    1.) Information/calculations concerning airborne concentrations of radioactive material are still listed in Maximum Permissible Concentrations (MPC's). MPC's were replaced by Derived Airborne Concentration values in the early 1990's.
    2.) Annual Audit- 10 CFR 20, Section 20.1101 "Radiation Protection Program" subpart (C) states: "The license shall periodically (at least annually) review the radiation protection program content and implementation." The only audit the program performs is a quarterly audit, which does not meet the requirements of this section. It was pointed out to Manchester Memorial staff that they should utilize NRC NUREG 1556 Volume 9, Specific Guidance for Medical Licensees, Appendix L, "Annual Program Audit" as a guide for his annual program audit.

THE FOLLOWING VIOLATION(S) OF THE REGULATIONS OF CONNECTICUT STATE AGENCIES AND/OR CONNECTICUT GENERAL STATUTES WERE IDENTIFIED

Action:

1. The Victorian XenoGuard instrument utilized to measure Xe-133 gas radioactivity will be removed from service. Recent correspondence with NRC noted that as long as compliance with 10 CRF 20 is demonstrated, it is not a requirement that a XenoGuard be utilized during Xe-133 ventilation scans. We will be transitioning to Tc-99m DTPA aerosol ventilation studies.
2. In the interim, a bag test will be performed monthly to measure the effectiveness of our Biodex Xenon trap until our transition to DTPA aerosols is completed.
3. Nuclear medicine technologists will be educated in trap effluent monitoring via "bag test" by the consulting nuclear medical physicist.
4. Nuclear medicine technologists will be educated in the use of Tc-99 DTPA aerosol.

Person Responsible: Administrative Director, Medical Imaging
Completion date: 9/30/18

The following is a violation of the State of Connecticut Public Health Code Section 19-13-D3 (e) Nursing Service (1) and/or (i) General (6) and/or (l) Infection Control.

20. Based on a tour of the surgical department, review of facility policies, observations and interview, the facility failed to ensure proper hair coverage in the restricted surgical suites. The finding includes:
    a. A tour of the surgical department was conducted with the Director of Perioperative Services on 5/15/18. Observations at 9:44 AM identified the ST (surgical technician) and the physician in OR #6 with bouffant hair covering on and hair not completely contained in the hair covering. Observations at 9:48 AM of OR #7 and/or 9:49 AM of OR #5 (both during total joint cases) and/or 9:55 AM of OR #1 identified the Anesthesia Provider and/or the Patient Care Assistant and/or the Physician's Assistant with beard and/or sideburns exposed. Observations at 9:51 AM noted the surgeon, during the surgical procedure, had donned a bouffant hair covering and hair was exposed at the nape of the neck.
    Interview with the Director of Perioperative Services on 5/15/18 at 9:46 AM indicated that the surgical area follows the standards of AORN (Association of Peri Operative Registered Nurses) and all hair must be enclosed. The facility policy for surgical attire identified that all head and facial hair will be covered by an approved disposable or reusable hat/hood in restricted and semi- restricted areas.

Action:

1. All OR staff were immediately re-educated regarding the requirement for appropriate coverage of hair and the containment of jewelry. This education was done via daily huddle.
2. All perioperative staff were educated via online education regarding the requirement for the appropriate coverage of hair and the containment of jewelry. This online education was assigned to all perioperative staff on 5/25/18.

Person Responsible: Assistant Director, Perioperative Services

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Audit: Audits will be conducted 5 times per month for 3 months to ensure that all hair and jewelry are appropriately contained.
Completion date: 8/31/18

The following is a violation of the State of Connecticut Public Health Code Section 19-13-D3 (e) Nursing Service (1) and/or (i) General (6) and/or (l) Infection Control.

21. Based on medical record reviews, review of facility policies, observations and interviews the facility failed to ensure appropriate glove changes and/or hand sanitization during patient care. The finding includes:
    a. A tour of the wound center was conducted on 5/16/18 with the Program Director and Patient #119's dressing change was observed at 10:02 AM. The observation identified that RN #15 removed her gloves after using a gloved hand to open a drawer and donned clean gloves without the benefit of sanitizing hands. She then proceeded to dress the Patient's wound. Interview with RN #15 on 5/16/18 at 10:20 AM indicated that she was nervous. The facility handwashing policy identified to sanitize hands after glove removal.

Action: The Wound Care Center nursing staff were re-educated on the process for performing a dressing change, including proper hand hygiene by reviewing policy 112 – Hand Hygiene, and Healogics policies for Hand Hygiene, Standard Precautions and Infection Control and Prevention.
Person Responsible: Program Director, Wound Care Center
Audit: Observe 5 dressing changes per month for 3 months for proper hand hygiene and dressing change technique.
Completion date: 9/30/18

The following are violations of the State of Connecticut Public Health Code Section 19-13-D3 (e) Nursing Service (1) and/or (i) General (6).

22. Based on observation during tour, the facility failed to ensure supplies that were ready for use had not expired and/or the environment was maintained in a sanitary manner. The findings include the following:
    a. During a tour of the Geri psychiatric unit on 5/16/18 at 10:30 AM, culture swabs stored in the supply room were observed with expiration dates in 10/2010, 10/2013, 3/16, 11/2016 and 2/2017.
    b. In addition, staple remover kits expired in 7/2015 and 3/2017, steri-strips expired in 7/2017 and glucose control solution expired in 11/2017.
    c. Tour of the Adolescent psychiatric unit on 5/16/18 at 9:30 AM identified balls of dust hanging off the observation mirror and the door frame to the nursing area had peeling paint.

Action Plan:
1. The Materials Management staff have been re-educated about rotating supplies in all areas

and removing expired products.
Person Responsible: Director, Materials Management
Audit: Audit once weekly for 3 months to ensure there are no expired products on the supply carts.
Completion date: 8/31/18

2. The environmental services staff have been re-educated about cleaning procedures on the Behavioral Health Unit.
3. A work order has been submitted to repaint the doorframe on the adolescent unit.

Person Responsible: Director, Environmental Services
Audit: Audit once weekly for 3 months for cleanliness on the Behavioral Health Unit.
Completion date: 8/31/18

The following is a violation of the State of Connecticut Public Health Code Section 19-13-D3 (g) Pharmacy (2) and/or (l) Infection Control.

23. Based on a review of Hospital documentation it was identified that the hospitals Infection Control and Prevention committee did not consistently review required testing in the pharmacy compounding area. The findings include:
    a. A review of the monthly Infection Control and Prevention committee meeting minutes dated December 2015 through February 2018 failed to indicate the results of environmental monitoring of the pharmacy compounding area were monitored and/or reviewed by Infection Prevention.
    Review of Environmental testing reports from January 2016 to current identified no actionable levels of environmental samples had been identified.
    During an interview with the Vice President of Quality and Patient Excellence on 5/16/18 at 12:15 PM he/she indicated environmental testing is completed and monitored by the Director of Pharmacy however in review of Infection Control and Prevention committee meeting minutes it was identified that from January 2016 through February 2018 the environmental testing had not been report and/or reviewed by Infection Prevention.
    Interview with the Infection Prevention Nurse on 5/16/18 at 1:30 PM identified the results had not been discussed in the Infection Control and Prevention committee meetings. He/she indicated the lack of reporting was recently identified as an issue during a separate facility review. The Infection Prevention Nurse indicated going forward he/she would gather the data pertaining to the pharmacy compounding area and the data will become a standing agenda item at the infection prevention committee meetings. The results will be reported every 6 months or should an issue be identified.
    Medical Staff Bylaws indicated the purpose and duties of the infection control committee shall be responsible for surveillance of infection potentials, review and analysis.

Action Plan: All results for environmental monitoring in the Pharmacy clean room will be brought to the Infection Control Committee (ICC) for review. Testing and subsequent results

of that testing will be completed every six months. The monitoring reports will include the results of the viable and nonviable results of the pharmacy compounding area. The monitoring reports will also include the status of the laminar flow hoods and biological safety cabinet. The next viable sampling is scheduled to be completed in September 2018. The hoods will be tested again in October 2018. The pharmacy representative will provide these monitoring results to the ICC on a routine basis. This has been placed as a recurring reporting item on the ICC agenda.
Person Responsible: Director, Pharmacy
Completion date: 9/30/18

The following is a violation of the State of Connecticut Public Health Code Section 19-13-D3 (c) Medical Staff (2)(B) and/or (d) Medical Records (3).

24. Based on medical record reviews, review of facility policies and interviews for one of six surgical patients (Patient #112), the facility failed to ensure that the anesthesia recovery assessment was performed timely. The finding includes:
    a. Patient #112 was admitted to the hospital on 5/15/18 for left eye surgery. The anesthesia record dated 5/15/18 identified that the Patient had monitored anesthesia care during the operative procedure. Review of nursing documentation dated 5/15/18 indicated that the Patient arrived in the recovery area at approximately 10:30 AM. Further review of the anesthesia record noted that the anesthesia recovery assessment by the anesthesiologist was conducted at 10:20 AM at the end of the surgical case and when the Patient was still in the OR.
    Interview with the Quality Manager on 5/15/18 at 11:11 AM indicated that the anesthesia recovery assessment should be later than the anesthesia end time and be performed when the patient was in the PACU (post anesthesia care unit). The facility policy for post-operative care identified that a post- anesthesia evaluation will be completed within 48 hours after surgery and the 48 hours begins at the point the patient is moved to the designated recovery room.

Action Plan: The Anesthesia staff was re-educated to provide a post-anesthesia assessment when sufficient time transpired since transfer from the Operating Room to time of post-procedure assessment by anesthesia and the patient is able to participate in this evaluation when possible.
Person Responsible: Chair, Department of Anesthesia
Audit: Audit 5 records per month for 3 months to ensure the assessment is done once a sufficient amount of time has transpired and the patient is able to participate in the evaluation when possible.
Completion date: 8/31/18

The following is a violation of the State of Connecticut Public Health Code Section 19-13-D3 (c) Medical Staff (2)(B) and/or (i) General (6).

25. *Based on clinical record review and interview. for one patient reviewed for medication

THE FOLLOWING VIOLATION(S) OF THE REGULATIONS OF CONNECTICUT STATE AGENCIES AND/OR CONNECTICUT GENERAL STATUTES WERE IDENTIFIED

errors (Patient #136), the hospital failed to ensure that an antipsychotic medication was ordered for the correct patient resulting in a medication error. The finding include the following:

a. Patient #136 presented to the Emergency Department (ED) on 3/18/17 at 8:14 PM with complaints of weakness and being dizzy for several weeks. Review of the physician note dated 3/18/17 at 10:48 PM indicated that the patient's symptoms were moderate to severe and worse when standing. The record identified that intravenous fluids were administered and that an "ambulatory trial" was completed however the patient felt that he/she was not able to go home. Review of a physician's order (MD #11) dated 3/18/17 at 12:56 AM directed to administer Seroquel 400 milligrams. The nursing progress note dated 3/19/17 indicated that Seroquel 400 mg was administered at 1:19 AM. A physician's order dated 3/19/17 at 1:49 AM directed that an EKG be performed for dizziness and giddiness. The EKG result identified that the patient had sinus bradycardia with a rate of 54 beats per minute. The nurse's note on 3/19/17 at 2:00 AM indicated that the patient was sleeping, answers questions appropriately and remained sluggish. The patient did not feel s/he could be discharged home and was subsequently admitted to the special observation unit at 3:09 AM.
A narrative note authored by the ED Director dated 3/20/17 at 10:35 AM identified that he met with the patient and significant other to inform them that while the patient was in the ED, s/he inadvertently had ordered and administered 400 mg of Seroquel and the patient was kept in the ICU for monitoring.
Interview with MD #10 on 5/18/18 at 9:51 AM stated on 3/18/17, MD #11 was asked by a RN to write a Seroquel order, however, the order was inadvertently ordered for Patient #136 resulting in a medication error. The patient did experience somulence and hypothermia and was admitted to the ICU as a precautionary measure.

Action Plan:
1. Medical Staff member involved was coached 1:1 on 3/20/17.
2. Blast email sent to all ED providers to re-educate regarding the importance of verifying patient ID when entering patient orders.
3. Staff re-educated in HRO behaviors that assist in open and clear communication between all team members.

Person Responsible: Chair, Department Emergency Medicine
Audit: Audit 5 records per month for 3 months for the appropriate medication being prescribed and administered to the appropriate patient.
Completion date: 9/30/18

The following is a violation of the State of Connecticut Public Health Code Section 19-13-D3 (b) Administration (2).

26. Based on clinical record review, interview and policy review, for one of four patients' reviewed for treatment planning (Patient #142), the hospital failed to ensure that a comprehensive individualized treatment plan was developed. The finding includes the following:

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a. Patient #142 was admitted on 5/4/18 after an intentional overdose with a history of borderline personality, post-traumatic stress disorder, and anxiety. Although there were notations by a representative from occupational therapy (OT) on 5/7/18 and 5/9/18 to update interventions and continue current plan, the record failed to reflect that OT completed a comprehensive evaluation. Review of the clinical record with the Nursing Director on 5/17/18 lacked evidence that a comprehensive occupational therapy (OT) evaluation was completed and/or that OT interventions were identified as part of the treatment plan. The policy indicated members of the treatment team are responsible for the discipline specific assessments. The OT assesses the patients work history, self-care abilities, leisure pursuits, and overall cognitive function within 72 hours of admission. The treatment plan specifies services and interventions needed to meet the goals and objectives derived from the assessments.

Action Plan: The Adult Behavioral Health unit staff have been re-educated regarding the need to develop individualized comprehensive treatment plans for both medical and behavioral health issues.
Person Responsible: Nurse Manager, Adult Behavioral Health
Audit: Audit 5 records per month for 3 months to ensure comprehensive individualized treatment planning is documented.
Completion date: 8/31/18

The following is a violation of the State of Connecticut Public Health Code Section 19-13-D3 (b) Administration (2) and/or (e) Nursing Service (1).

27. Based on clinical record review, interview and policy review, for one of four patients' reviewed for implementation of the treatment plan, (Patient #141), the facility failed to ensure that the treatment plan was revised weekly in accordance with policy. The finding includes the following:
    a. Patient #141 was admitted on 5/3/17 with explosive behavior with a history of traumatic brain injury and Diabetes. The clinical record indicated that the assessments were completed on 5/4/18. Review of the clinical record with the Nurse Manager on 5/18/18 at 12:00 PM indicated that the treatment team update (log) was completed on 5/15/18, 11 days after the initial plan. Interview with the Manager on 5/18/18 at 12:15 PM indicated that the treatment plans are to be updated as needed and/or at least every seven days.
    Review of the treatment planning policy failed to reflect when the treatment plan should be reviewed and/or updated. The policy indicated that the treatment plan specifies the services and interventions to meet the goals and objectives.

Action Plan: The treatment planning policy is being revised to indicate that treatment plans are to be updated at least every 7 days. Staff will be educated regarding the requirement to update treatment plans at least every 7 days.
Person Responsible: Nurse Manager, Adult Behavioral Health
Audit: Audit 5 records per month for 3 months to ensure treatment plans are updated at least

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every 7 days.
Completion date: 9/30/18

The following is a violation of the State of Connecticut Public Health Code Section 19-13-D3 (b) Administration (2).

28. Based on clinical record review, interview and policy review, for one of four patients reviewed for assessments (Patient #142), the facility failed to ensure that an occupational therapy (OT) evaluation was completed. The finding includes the following:
    a. Review of Patient #142's clinical record on 5/17/18 with the Nursing Director indicated that the patient was admitted on 5/4/18. The clinical record indicated that the Nursing, Physician and Social Work assessments were completed on 5/4/18. The record failed to reflect that a comprehensive OT assessment was completed.
    The policy indicated members of the treatment team are responsible for the discipline specific assessments. The OT assesses the patients work history, self-care abilities, leisure pursuits and overall cognitive function within 72 hours of admission.

Action Plan: OT staff has been educated about the need to add their assessment to the patient's chart within 72 hours of admission.
Person Responsible: Nurse Manager, Adult Behavioral Health
Audit: Audit 5 records per month for 3 months to ensure the OT assessment is documented within 72 hours of admission.
Completion date: 9/30/18

The following are violations of the State of Connecticut Public Health Code Section 19-13-D3 Short Term Hospitals, General and Special (a) Physical Plant (4) & (i) General (6).

29. During a tour and subsequent documentation review of the Manchester Memorial Hospital on 05/14/18 through 05/29/18, the following was observed:
    a. The surveyor was not provided with documentation Engineering Director that indicated that the deficiencies noted on the report for infrared inspection and testing of the facilities electrical panels throughout the facility identified as being high priority had been corrected.
    b. The surveyor was not provided with documentation by the Engineering Director that indicated that the deficiencies noted on 02/14/18 report for the inspection and testing of the piped in medical gas system had been corrected i.e. master alarms, manifolds, missing zone valves as required by NFPA 99.

Action Plan: Eight of the deficiencies were corrected by 6/13/18. The final deficiency will be corrected by 9/30/18.
Person Responsible: Chief Operating Officer and Director of Engineering.
Completion date: 9/30/18

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The following is a violation of the State of Connecticut Public Health Code Section 19-13-D3 (a) Physical Plant (4) and/or (i) General (6).

30. The facility did not ensure that piped in medical gas systems are in compliance with NFPA 99, 5.1.14.2 Maintenance Programs.
On 05/29/18 at 1:00 PM, the surveyor was not provided with documentation by the Engineering Director that indicated that the deficiencies noted on 02/14/18 report for the inspection and testing of the piped in medical gas system had been corrected i.e. master alarms, manifolds, missing zone valves as required by NFPA 99.
The facility did not ensure that electrical wiring and equipment is in accordance with NFPA 70, "National Electrical Code", as required by section # 9.1.2 of the referenced, "Life Safety Code"
On 05/29/18 at 1:30 PM, the surveyor was not provided with documentation by the Engineering Director that indicated that the deficiencies noted on the report for infared inspection and testing of the facilities electrical panels throughout the facility identified as being high priorty had been corrected.

Action Plan: The Chief Operating Officer and Director of Engineering have contracted with a vendor to correct deficiencies in the medical gas system to maintain compliance. Quotes were obtained by June 29, 2018.
Person Responsible: Chief Operating Officer and Director of Engineering
Completion date: 9/30/18

The following is a violation of the State of Connecticut Public Health Code Section 19-13-D3 (b) Administration (2) and/or (c) Medical Staff (2)(B) and/or (i) General (6).

31. Based on medical record reviews, review of facility policies and interviews for one of three patients who had surgery involving an explant (Patient #126), the facility failed to ensure that the entire explant was removed as per the surgical consent. The finding includes:
a. Patient #126 was admitted for laparoscopic band removal on 9/25/17. The consent form for 9/25/17 was signed by MD #12 and Patient #126 and identified robotic Roux- EN- Y gastric bypass and robotic removal of gastric band and port. The operative record and/or operative report dated 9/25/17 noted that the final count was correct and/or the adjustable gastric band and port were removed robotically and gastric bypass were performed by MD #12. The upper GI (gastrointestinal) series dated 9/26/17 identified that a catheter device was observed in the right upper abdomen. MD #12's progress note dated 9/26/17 indicated that the UGI noted a band in the abdominal cavity, Patient #126 was notified and band extraction surgery was planned. The operative report by MD #12 dated 9/26/17 identified that the retained lap band was removed. Interview with MD #12 on 5/17/18 at 11:08 AM indicated that per. usual, once the gastric band was removed off of the Patient's stomach, the band was "put to the side" of the Patients abdomen, the gastric bypass was performed and the band was never removed from the Patient's abdominal cavity in error. MD #12 further noted that although counts of items brought into the OR were always performed, the count never included something

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removed from a patient that the patient had come into the OR with (explant). The facility policy for retained surgical items identified that the surgeon will perform a methodical wound exploration when closing counts are initiated.
Subsequent to the event, the facility submitted a CAP that included revision of the Universal Protocol sheet to account for explants at sign off, staff education and review of the event as a safety event by the Surgical Services Leadership. The facility was found to be compliant with the plan as submitted.

Action Plan:

1. Findings reviewed with surgeon of case on 9/26/17.
2. Findings reviewed with Surgical Services Leadership on 10/23/17.
3. Education provided to General Surgery staff regarding the process of accounting for explants at the time of sign out by 12/4/17.
4. One on one education was provided to involved staff on 9/26/17.
5. OR staff was educated to:
    a. Review completed procedure to assure that all parts of the procedure have been completely carried out at the time of sign out.
    b. Assure that all explants are accounted for at the time of sign out
    c. Work together as a team to cross check that the wound is clear of all items prior to wound closure
    d. This education was provided via an on-line education system.

Person Responsible: Director, Perioperative Services
Audit: Review 5 surgical records of patients requiring explant for completion of sign out on Universal Protocol form.
Completion date: 1/31/18

The following is a violation of the State of Connecticut Public Health Code Section 19-13-D3 (i) General (6) and/or (l) Infection Control.

32. Based on a tour of the endoscopy unit, review of manufacturer's recommendations, observations and interviews the facility failed to ensure that endoscopes were properly cleaned with enzymatic solution. The finding includes:
    a. A tour of the endoscopy unit was conducted with the Ambulatory Services Manager on 5/15/18. Observation of the scope reprocessing area at 11:33 AM identified a sink marked with a water "fill" line and a sign above the sink denoting that the line reflected a 4 gallon fill. Interview with the CSP (Certified Sterile Processor) on 5/15/18 at 11:33 AM indicated that she uses 2 ounces of enzymatic in the sink per the 4 gallons of water to initially clean the scopes. Observation of water added to the fill line identified that 6 gallons of water and not 4 gallons were present in the sink when water reached the fill-line marking. Review of the enzymatic manufacturer's recommendations and interview with the CSP identified that an additional ounce of enzymatic cleaner was needed when the sink was filled with water to the fill line. The manufacturer's recommendations for Acedcide enzymatic cleaner directed 1/2-1 ounce of enzymatic cleaner per gallon of

water.

Action Plan: The endoscopy assistants have been educated to follow the manufacturer's guidelines when preparing the enzymatic pre-soak on May 15, 2018. All endoscopy assistants will be monitored when pre-cleaning endoscopes after the delivery of the scope to the processing room beginning 6/1/18.
Person Responsible: Nurse Manager, GI Department
Audit: Audit the preparation of the pre-soak 5 times per month for 3 months to ensure accurate preparation of the enzymatic pre-soak
Completion date: 8/31/18